[redacted]

October 25, 2023

VIA ECF

Hon. Cathy L. Waldor, U.S.M.J.
U.S. District Court for the District of New Jersey
50 Walnut Street, Room 4040
Newark, NJ 07102

Re: ***Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC***
No. 2:22-cv-02632 (ES) (CLW)

Dear Judge Waldor:

We submit this joint letter on behalf of the parties in the above-captioned matter pursuant to Local Rule 37.1 and the Court's Civil Case Management Order. Defendant Save On SP, LLC ("SaveOnSP") asks the Court to compel Plaintiff Johnson & Johnson Health Care Systems, Inc. ("JJHCS") to produce documents from the custodial files of the twelve custodians discussed below.

JJHCS asserts that it has fully complied with its discovery obligations, as demonstrated by the very documents SaveOnSP cites below. SaveOnSP is seeking nothing less than a complete restart of custodial discovery—a request that would never have been justified and certainly is not justified now, more than a month after the passage of the Court's already-twice-extended deadline for substantial completion of document production.

SaveOnSP asserts that JJHCS's position is meritless. While SaveOnSP has reviewed and produced massive numbers of documents, JJHCS has done very little and done it slowly, withholding most of its production until June. Its documents show that the requested individuals are overwhelmingly likely to have unique, relevant material, yet JJHCS has resisted adding them as custodians through a prolonged meet-and-confer process. JJHCS cannot bootstrap its failure to designate these individuals earlier into an excuse not to do so now. JJHCS responds that SaveOnSP has no basis to complain that JJHCS did not substantially complete its production "until June"—nearly five months ago, and three months before SaveOnSP did so. And SaveOnSP's procrastination goes back further than that: JJHCS first declined to add some of the requested custodians in March, more than half a year ago. JJHCS did so because its current custodians provide ample coverage of the disputed issues in this case. Thus, SaveOnSP's motion is not only inexcusably late, it also fails on the merits.

The parties have met and conferred in good faith but were unable to resolve this dispute.

SaveOnSP's Position

This letter highlights the dramatic imbalance between the parties' approach to discovery in this case. SaveOnSP has responded to 94 document requests from JJHCS, designated 28 custodians, reviewed over 700,000 documents, and produced over 200,000 documents (plus extensive call records and claims data) on a wide range of subjects. Throughout, JJHCS has insisted that this massive effort is not unduly burdensome for SaveOnSP and is proportional to the needs of this complex litigation.

At the same time, however, JJHCS has resisted the production of documents from its own files. As recent letters to the Court show, JJHCS has either withheld, or declined to conduct a reasonable search for, key documents going to (1) the terms and conditions that JJHCS claims SaveOnSP induced patients to breach, Dkt No. 146, (2) key financial information including about its return on investment from CarePath, Dkt No. 150, (3) critical information within Janssen, the Johnson & Johnson division that makes the drugs at issue, Dkt No. 162, and (4) documents showing its efforts to identify members of plans advised by SaveOnSP—which could dispense of its claims by showing that it failed to mitigate its supposed damages. At last count JJHCS has reviewed only 20,000 documents, June 27, 2023 Hr'g Tr. at 65:14-21, and produced only about 16,000.

The difference is stark:

	SaveOnSP	**JJHCS**
Document Requests Responded To	94	57
Custodians	28	17
Documents Reviewed	~700,000	~20,000
Documents Produced	~200,000	~17,000

Relevant to this application, JJHCS has failed to designate appropriate document custodians. While it has designated 16 individuals as custodians, Ex. 1 (Feb. 6, 2023 Ltr.); Ex. 2 (Mar. 16, 2023 Ltr.), the vast majority of its production—over 12,500 documents—came from only ***four*** custodians or from noncustodial files. Its other twelve custodians account for a total of only about 3,000 documents. This strongly indicates that JJHCS has not designated key individuals with relevant materials.

The merits of each custodian are detailed below. We suggest that these merits be viewed in context with the one-sided nature of the burdens the parties have shouldered in complying with

discovery. JJHCS now refuses to add as custodians the twelve individuals discussed below—despite overwhelming evidence that they would possess unique, relevant documents.[1] SaveOnSP asks the Court to compel JJHCS add these individuals as custodians. In the context of the burden JJHCS has imposed on SaveOnSP, any claim of burden by JJHCS cannot be countenanced.

Members of the Janssen Americas Leadership Team

SaveOnSP asks that JJHCS add three members of the Janssen Americas Leadership Team ("JALT").[2] The JALT "supports and drives commercial strategies, market access, and provider and patient support for [Janssen's] medicines."[3] [redacted] Ex. 8 (JJHCS_00002618); [redacted]" Ex. 9 (JJHCS_00002616). If the JALT approved this letter, it almost certainly had to approve (or have input into approving) changes to the terms and conditions themselves—which JJHCS alleges SaveOnSP induced patients to breach. Compl. ¶ 108. JJHCS's supplemental interrogatory responses also confirm that the JALT had "[redacted]," which would include CarePath's budget—the viability of which JJHCS alleges is jeopardized by SaveOnSP's services. Ex. 10 at 17 (July 28, 2023 Suppl. Resps. & Objs.); Compl. ¶ 114. [redacted]

[1] On July 17, 2023, based on JJHCS's interrogatory responses and SaveOnSP's review of JJHCS's production, SaveOnSP requested that JJHCS add additional custodians. Ex. 3 (July 17, 2023 Ltr.). JJHCS offered to add Quinton Kinne and Daphne Longbothum in exchange for SaveOnSP adding a single custodian if SaveOnSP would drop all other custodian requests. Ex. 4 (July 28, 2023 Ltr.). SaveOnSP agreed to add Zulqarnain but refused to drop its requests for other relevant custodians. Ex. 5 (Aug. 23, 2023 Email Exchange). On August 28, 2023, SaveOnSP requested that JJHCS add 13 custodians. Ex. 6 (Aug. 28, 2023 Ltr.). In response, on September 11, 2023, JJHCS agreed to run only four search terms over Mr. Silas Martin as a limited custodian. Ex. 7 (Sept. 11, 2023 Ltr.).

[2] JJHCS asserts that it need not add any member of the JALT as a custodian because the apex doctrine shields the production of documents from top-level executives. Not so. "[T]he 'apex doctrine,' while it may be applicable to depositions, is not a protective shield that prohibits document discovery from high-ranking executives." *Sandoz, Inc. v. United Therapeutics Corp.*, 2020 WL 13830525, at *3 (D.N.J. Nov. 16, 2020) (citing *Nat'l Labor Relations Bd v. 710 Long Ridge Rd Operating Co. II, LLC*, 2020 WL3026523 at *2 (D.N.J. June 5, 2020)). Neither of the cases cited by JJHCS is applicable here. *Sugg v. Virtusa*, 2020 WL 6585872, (D.N.J. Nov. 10, 2020) does not even mention the apex doctrine. The Court in *Sugg* determined it would be duplicative to add the CEO and President of defendant where defendant had already agreed to add as a custodian the head of every department and 32 total custodians. *Id.* at *2. By contrast, SaveOnSP does not seek the documents of Joaquin Duato, the CEO of Johnson & Johnson, or Alex Gorsky, the former CEO; instead, it seeks individuals who demonstrably had a role in CarePath. In *Lauris v. Novartis AG*, 2016 WL 7178602, at *3 (E.D. Cal. Dec. 8, 2016), the Court rejected plaintiffs' argument that the apex doctrine can be used categorically to avoid e-discovery of high-level executives.

[3] Scott White, LINKEDIN, https://www.linkedin.com/in/scott-white-37860b7?orignal_referer=https%3A%2F%2Fwww.bing.com%2F (last visited June 23, 2023).

Ex. 11 (JJHCS_00041213); Ex. 12 (JJHCS_00041215)

Blasine Penkowski. Penkowski, the Chief Strategic Customer Officer of JJHCS, *see* Ex. 13 (JJHCS_00000106),
to SaveOnSP, Ex. 14 (JJHCS_00101641) (
); Ex. 15 (JJHCS_00084221)
Ex. 16 (JJHCS_00101570) (
, Ex. 17 (JJHCS_00083216).
See Ex. 18 (JJHCS_00001830); Ex. 19 (JJHCS_00001668) (
.

Discovery shows that JJHCS's assertion in the June 23, 2023 joint letter that Penkowski's documents are likely captures by Katie Mazuk's documents is untrue: (1) Penkowski appears on many relevant email threads without Mazuk, *see* Ex. 20 (JJHCS_00027236)
Ex. 21 (JJHCS_00026852)
; (2) Penkowski sent and received emails with to which no other custodian is a party, Ex. 22 (JJHCS_00133487)
; (3)
Ex. 23 (JJHCS_00026519), and
, Ex. 24 (JJHCS_00074697)—indicating that she directly received unique information about SaveOnSP and other entities that JJHCS deems to be maximizers; (4) she signed many contracts with TrialCard outlining TrialCard's duties for JJHCS in relation to CarePath, Ex. 25 (JJHCS_00025908); Ex. 26 (JJHCS_00025517) (
); Ex. 27 (JJHCS_00025532) ( ); Ex. 28 (JJHCS_00024511) ; Ex. 29 (JJHCS_00025594) ( )—indicating that she has unique information about the services TrialCard, the vendor that JJHCS used as the primary point of patient contact for CarePath, *see, e.g.*, Ex. 30 (JJHCS_00002481),
, Ex. 31 (JJHCS_0003353).

Scott White. White, a member of the JALT and the Company Group Chairman for North America Pharmaceuticals Johnson & Johnson, *see* Ex. 32 (JJHCS_00001542),
see, e.g., Ex. 33 (JJHCS_00011154) (
; Ex. 11 (JJHCS_00041213)
(
). He

was part of the subset of the JALT that received relevant information regarding CarePath and SaveOnSP. *See* Ex. 18 (JJHCS_00001830); Ex. 19 (JJHCS_00001668) ([redacted]), Ex. 34 (JJHCS_00001704), further indicating his involvement in JJCHS's response to SaveOnSP.

Discovery has shown that, contrary to JJHCS's assertion in its June 23, 2023 joint letter, his documents likely would not be captured by Mazuk's documents: (1) [redacted], Ex. 35 (JJHCS_00100210), *see also* Ex. 36 (JJHCS_00100213) ([redacted])—indicating he has unique information about such complaints; (2) he appears on email threads without Mazuk, *see* Ex. 37 (JJHCS_00132336) ([redacted]); Ex. 38 (JJHCS_00132346) ([redacted]); and (3) he signed work orders and change orders with TrialCard, Ex. 39 (JJHCS_00039767); Ex. 40 (JJHCS_00039772); Ex. 41 (JJHCS_00039696); Ex. 42 (JJHCS_00039374); Ex. 43 (JJHCS_00039378); Ex. 44 (JJHCS_00039382); Ex. 45 (JJHCS_00039625); Ex. 46 (JJHCS_00039879)—indicating that he had information about the services TrialCard provides to JJHCS and control over an aspect of the operation of CarePath, with which Mazuk had no involvement.

Ernie Knewitz. Knewitz, the Regional Pharmaceutical Communications Leader, the Americas, and a member of the JALT, Ex. 47 (JJHCS_00001859), was involved in the marketing of Janssen Drugs and of CarePath. [redacted] " Ex. 10 at 12 (July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories). He was included on multiple JALT communications regarding CarePath, Ex. 48 (JJHCS_00001857). [redacted] Ex. 49 (JJHCS_00083266). [redacted] Ex. 11 (JJHCS_00041213), [redacted] Ex. 34 (JJHCS_00001704).

Brand Employees

SaveOnSP ask that JJHCS be compelled to add two employees as custodians who worked on Janssen's "brands" for Janssen drugs at issue in this case, and who had a hand in decisions involving CarePath.

Karen Lade. Lade is the former Product Director, Integrated Customer Solution, Patient Affordability Strategy at Janssen Immunology,[4] Ex. 50 (JJHCS_00002688). Ex. 51 at 62-66 (JJHCS_00073073). Ex. 52 (JJHCS_00083183); *see also* Ex. 53 (JJHCS_00083894) (” Ex. 54 (JJHCS_00083180) , Ex. 55 (JJHCS_00105296). , Ex. 56 (JJHCS_00045468).

Discovery has shown that JJHCS's assertions that Lade's documents would be captured by other custodians is untrue: (1) Lade sent emails regarding CarePath in 2016 to Jeffcoat, attaching other emails regarding CarePath with no custodian as a party, Ex. 57 (JJHCS_00083929) (attaching JJHCS_00083930); (2) she sent emails regarding CarePath enrollment guides, which includes the goals of CarePath (to retain patients), Ex. 58 (JJHCS_00083930)— ; (3) Ex. 59 (JJHCS_00083931); *see also* Ex. 60 (JJHCS_00083932) ((4) her prominent leadership role indicates that she likely has unique communications: she sent an email directing various marketing, Department of Medical Education, and Sales Learning, and Development Team Leaders on approved CarePath materials. Ex. 52 (JJHCS_00083183). Ex. 61 (JJHCS_00134403) ( ).

Juliette Deshaies. Deshaies was the Group Product Director of the ERLEADA Patient Experience. Juliette Deshaies, LINKEDIN, https://www.linkedin.com/in/juliette-deshaies-1132b44 (last visited May 9, 2023). As JJHCS represented to the Court, Deshaies worked on the marketing of multiple Janssen Drugs at issue, June 23, 2023 Joint Ltr. at 11, Dkt. No. 127 (Deshaies's "primary responsibilities related to the marketing of Simponi Aria, Stelara, and Tremfya"). , Ex. 62 (JJHCS_00083836); *see also* Ex. 63 (JJHCS_00083838). , Ex. 64 (JJHCS_00083826),

[4] Ms. Lade does not appear on any organizational chart produced to date by JJHCS.

[redacted] And she had a call with Alison Barklage without any current custodians [redacted] *see, e.g.*, Ex. 65 (JJHCS_00104243)—indicating she has unique documents on offering of CarePath for Erleada.

Deshaies was also heavily involved in other aspects of CarePath: (1) she worked closely with Adrienne Minecci on CarePath for Deshaies' "brands" (the drugs she marketed), Ex. 66 (JJHCS_00059500); (2) she worked with Minecci on patient communications that included CarePath's terms and conditions, Ex. 67 (JJHCS_00059501) at 3 ([redacted]), 7 ([redacted]); (3) she was asked for feedback on a presentation regarding a brochure for patients taking Erleada and using CarePath funds, Ex. 64 (JJHCS_00083826), which included CarePath's terms and conditions; (4) she apparently oversaw the CarePath program for the Janssen drug Simponi Aria, Ex. 68 (JHCS_00110089); Ex. 69 (JJHCS_00114605); Ex. 70 (JJHCS_00061959); Ex. 71 (JJHCS_00061961), including reviewing and seeking approval for program language, Ex. 70 (JJHCS_00061959), and refreshing the patient website for Simponi Aria to reflect CarePath program language, Ex. 69 (JJHCS_00114605); and (5) she provided direction on strategy [redacted]" Ex. 72 (JJHCS_00011144-45).

While JJHCS asserted that DeShaies's documents would be cumulative of those in the files of custodians Spilios Asimakopoulos, discovery shows otherwise: She received an email from McCann [redacted], Ex. 73 (JJHCS_00069842)—indicating that she has unique documents regarding the offering of CarePath for Stelara.

CAP Program

As described in more detail in a forthcoming submission, [redacted] Ex. 74 (JJHCS_00133549) ([redacted]); Ex. 75 (JJHCS_00040622) ([redacted]) [redacted] Ex. 12 (JJHCS_00041215). As part of this program, JJHCS changed CarePath's terms and conditions ("T&Cs") applicable to its drugs Stelara and Tremfya to (1) reduce the maximum amount J&J would pay patients who were members of maximizers from $20,000 to $6,000, and (2) eliminate payments to patients "who are members of health plans that claim to eliminate their out-of-pocket

costs."[5] *See, e.g.* Dkt. No. 31-7. Ex. 31 (JJHCS_0003353). Documents regarding these efforts—both actions taken and not taken—are crucial to SaveOnSP's mitigation and acquiescence defenses. *See* Aff. Defs. ¶¶ 24-29.

Quinton Kinne. Kinne is the Senior Manager for Pharmacy Monitoring and Program Compliance as part of the Strategic Customer Group of JJHCS, Ex. 76 (JJHCS_00000358). s, Ex. 77 at 15-16 (Jan. 17, 2023 JJHCS's Resps. to SaveOnSP's First Interrogatories). , Ex. 78 (JJHCS_00010098), , Ex. 79 (JJHCS_00011143).

Kinne is likely to have unique documents regarding the CAP program: Ex. 80 (JJHCS_00035757)— Ex. 81 (JJHCS_00008989)—indicating that he has unique documents regarding JJHCS's responses to SaveOnSP; (3) Kinne received emails with no other custodians on them regarding the amount of available copay assistance for Tremfya (Ex. 83 (JJHCS_00139287)— , *see, e.g.*, Ex. 84 (JJHCS_00135344) ( ); Ex. 85 (JJHCS_00135351) ( )

[5] . *See, e.g.*, Ex. 82 (JJHCS_00104708) ( ); *see also* Ex. 64 (JJHCS_00083826) (. Presumably JJHCS made a business decision that limiting copay assistance funds — in a way that might have mitigated its purported damages in this action—would be harmful to its business. *See* Ex. 64 (JJHCS_00083826). This evidence is crucial to SaveOnSP's acquiescence and mitigation defenses: JJHCS cannot seek damages from SaveOnSP when it contemplated, but decided against implementing changes which would have prevented those damages from accruing in the first place.

[redacted]

JJHCS has not disputed that Kinne has relevant documents. It offered to add him as a custodian if SaveOnSP would add Ayesha Zulqarnain and drop all other requests for other custodians. Moreover, despite refusing to add Kinne as a custodian, JJHCS appears to have produced relevant documents from his files. *See, e.g.*, Ex. 86 (JJHCS_00139046) ([redacted]; Ex. 87 (JJHCS_00139049) ([redacted]).

Daphne Longbothum. Longbothum is the Manager, Patient Affordability & Access Solutions, Pulmonary Hypertension, for the Janssen Pharmaceutical Companies of Johnson & Johnson, Daphne Longbothum, LINKEDIN, https://www.linkedin.com/in/daphne-longbothumb734862b (last visited Aug. 27, 2023).

Longbothum is likely to have unique documents regarding the CAP program: [redacted] Ex. 88 (JJHCS_00008591); [redacted] Ex. 89 (JJHCS_00001391); Ex. 90 (JJHCS_00001464); [redacted] Ex. 91 (JJHCS_00008466); Ex. 92 (JJHCS_00008584); Ex. 93 (JJHCS_00008634); [redacted] Ex. 94 (JJHCS_00008501); [redacted] Ex. 90 (JJHCS_00001464)—[redacted] Ex. 95 (JJHCS_00008802)—[redacted] Ex. 96 (JJHCS_00008838)—[redacted].

JJHCS has not disputed that Longbothum has relevant documents. It offered to add her as a custodian if SaveOnSP would add Ayesha Zulqarnain and drop all other requests for other custodians.

William Shontz. Shontz is Associate Director, Patient Access and Affordability Solutions, Oncology at Johnson & Johnson. William (Will) Shontz, LINKEDIN, https://www.linkedin.com/in/williamtshontz (last visited May 9, 2023).

Shontz is likely to have unique documents regarding the CAP program, especially as to whether [redacted] Ex. 98 (JJHCS_00029831-34); *see also* Ex. 99 (JJHCS_00029829) ([redacted] Ex. 100 (JJHCS_00029838); [redacted] Ex. 64 (JJHCS_00083826); [redacted], Ex. 101 (JJHCS_00104674); [redacted] Ex. 102 (JJHCS_00029708); [redacted] Ex. 103 (JJHCS_00030300) [redacted] Ex. 104 (JJHCS_00002355); [redacted] Ex. 105 (JJHCS_00133520), [redacted] Ex. 82 (JJHCS_00104708) [redacted].

Shontz also worked on the marketing of CarePath. [redacted]" Ex. 106 (JJHCS_00104322); *see also* Ex. 107 (JJHCS_00104319); Ex. 108 (JJHCS_00044074). [redacted] Ex. 106 at 13 (JJHCS_00104322).

While JJHCS asserts that Shontz's documents would be captured by those of other custodians, discovery shows this is untrue: (1) Shontz received several relevant communications that were not sent to other custodians, Ex. 109 (JJHCS_00005897) ([redacted]); Ex. 110 (JJHCS_00034500) ([redacted] Ex. 111 (JJHCS_00034561) (same)—indicating that he received relevant communications directly; (2) he appears on an email regarding CarePath for Zytiga that was not sent to any other custodian, Ex. 105 (JJHCS_00133520) (later forwarded to a custodian); (3) he apparently gave an approval [redacted] Ex. 112 (JJHCS_00030136)—indicating that he either had independent approval authority or the authority to act in McCool's stead; (4) when McCool was out of the office, she directed people to reach

out to Shontz, Ex. 113 (JJHCS_00001202), and later emails in that thread do not include McCool or McKelvey; and (5) many emails include Shontz but neither McKelvey or McCool, *see, e.g.*, Ex. 109 (JJHCS_00005897) ( ); Ex. 114 (JJHCS_00008556) ( ).

Alison Barklage. While JJHCS asserted in its July 28, 2023 letter that Barklage was a "JJHCS contractor during the relevant period with administrative responsibilities," Ex. 4 (July 28, 2023 Ltr.), LinkedIn states that from 2004 to 2007 she was a Consulting Director at Johnson & Johnson and from 2011 to the present has been the President of AKB Consulting (her own company), in which she "delivers change & project management consulting for large pharmaceutical companies" and "support[s] senior stakeholders with project management on critical business initiatives, including issue identification, stakeholder engagement & communications, project planning, dashboard status reporting, and success measurement plans."[6] During a September 20, 2023 meet and confer, SaveOnSP asked JJHCS to define what it meant by administrative responsibilities, and whether by that JJHCS meant that she was an administrative assistant, but JJHCS refused to clarify, repeating that she was a contractor with administrative responsibilities.

, Ex. 115 (JJHCS_00084174); *see also* Ex. 116 (JJHCS_00084176); Ex. 117 (JJHCS_00084504); Ex. 118 (JJHCS_00084426); Ex. 119 (JJHCS_00084507); Ex. 120 (JJHCS_00133545) (e); Ex. 74 (JJHCS_00133549).

Ex. 121 (JJHCS_00135283); *see also* Ex. 122 (JJHCS_00135284)—

Barklage also performed other relevant substantive work regarding CarePath: (1)

[6] Alison Barklage, MHSA, LINKEDIN, https://www.linkedin.com/in/alison-barklage?challengeId=AQFbgDDvMikQdAAAAYotJLka16VvfLHioohPKqHkyHQq8-x8kcseu4DpAyvTdJVIQsr0EHO_irv6te5zBl4ZpmiokUGq-gnyfw&submissionId=a11fb285-55a7-7e17-f8f8-22be33e1a736&challengeSource=AgEdBx4PytP1swAAAYotJO8HtPee3A-dt2H1mjjKjMQQi7fuI_H-PqNqfXcY7m8&challegeType=AgEEI2s1TqMI3QAAAYotJO8LI_gIY5uJ0J4qMy9wQdzaZGx4qhGD2YI&memberId=AgGbLaHzLoTyeAAAAYotJO8OUy_dh7q02DhaOAmyeVtVWiY&recognizeDevice=AgFf9b5VuiQntgAAAYotJO8SLSPSWYD0Dv5BdP2y1X2lUqTey2kg (last visited Aug. 25, 2023).

Ex. 123 (JJHCS_00084681)—[redacted] Ex. 124 (JJHCS_00117387) [redacted], Ex. 125 (JJHCS_00060430).

While JJHCS asserts that her documents would be captured by Jeffcoat's documents, discovery shows otherwise: (1) she was the only sender of an email to Jeffcoat regarding [redacted] Ex. 123 (JJHCS_00084681)—indicating she has unique information about CarePath's enrollment; (2) she is part of a series of emails [redacted] Ex. 126 (JJHCS_00069171)—indicating she has unique information about the offering of CarePath for Darzalex; and (3) she sent a presentation [redacted] Ex. 127 (JJHCS_00069174)—indicating that she has unique information regarding JJHCS's communication efforts regarding CarePath.

John Hoffman. Hoffman was as the former head of Health Policy & Advocacy at Johnson & Johnson, in which role he "help[ed] to enact state legislation prohibiting non-medical switching and copay accumulator and maximizer programs".[7] [redacted] Ex. 10 at 23-24 (July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories). [redacted], Ex. 20 (JJHCS_00027236); Ex. 21 (JJHCS_00026852). [redacted], Ex. 16 (JJHCS_00101570).

JJHCS claims that he only was involved in communications related to this action, and was not involved in the marketing of CarePath "on a regular basis," Ex. 7 (Sept. 11, 2023 Ltr.), but the

---

[7] John Hoffman, LINKEDIN, https://www.linkedin.com/in/john-hoffman-b788147?challengeId=AQHIg4eOVl86lAAAAYovUZQ9SsGyvdo2HYtutCig6Xv1wLmAESYejIZNNUm5tj_f3xXdkNRIsO2pKckOxX0yNv2iDuWS_CHTJA&submissionId=80ad3273-86c8-7e17-a1fe-77f347742717&challengeSource=AgH1X6LAia67HwAAAYovU4AHBhdazZxe-czPqZAJoV21oKYm5wu7ZSjcwBLBnKw&challegeType=AgGRK-8FFEdBJgAAAYovU4AJHwvS8UwxYtNjfsJqMYjqd1mPyaC3LvM&memberId=AgGo7hRMgBgeJAAAAYovU4AMGQy0lcdLCH7f9bLEylRddVo&recognizeDevice=AgGseyLBagE6qAAAAYovU4APYASa3jZyEgK90MKG0BoiwT_PF69U (last visited Aug. 25, 2023)

documents cited above show otherwise: [redacted] Ex. 128 (JJHCS_00133499); *see also* Ex. 129 (JJHCS_00133495) ([redacted], Ex. 130 (JJHCS_00133350).

L.D. Platt. Platt, the head of federal public affairs for Janssen,[8] [redacted] Ex. 131 (JJHCS_00100535); Ex. 132 (JJHCS_00008448); Ex. 133 (JJHCS_00008451); Ex. 134 (JJHCS_00037157). [redacted] Ex. 135 (JJHCS_00008447). [redacted] Ex. 136 (JJHCS_00027996); Ex. 137 (JJHCS_00008450); Ex. 138 (JJHCS_00037156). [redacted] Ex. 139 (JJHCS_00027974). [redacted] Ex. 19 (JJHCS_00001668).

JJHCS claims that he only was involved in communications related to this action, and was not involved in the marketing of CarePath "on a regular basis," Ex. 7 (Sept. 11, 2023 Ltr.), but the documents cited above show otherwise. JJHCS also asserts that L.D. Platt's documents are likely privileged, but during the September 20, 2023 meet and confer, JJHCS admitted that he is not an attorney. JJHCS claimed that he communicated with outside counsel, but it cites no authority showing that this is a sufficient basis to withhold his documents.

Leigh Wyszkowski. Wyszkowski is the Director of Fee for Service (FFS) Execution & Cut Supplier Management as part of the Strategic Customer Groups, Ex. 140 (JJHCS_00000346). [redacted] Ex. 146 (JJHCS_00026553). [redacted] Ex. 141 (JJHCS_00000551)—indicating that she was involving with JJHCS's response to SaveOnSP, Ex. 142 (JJHCS_00000641) ([redacted], Ex. 143 (JJHCS_00000553), [redacted]

[8] Lawrence (L.D.) Platt, LINKEDIN, https://www.linkedin.com/authwall?trk=bf&trkInfo=AQHF2DjyG-NfLyQAAAYr4P9MYCPQ3XZlhNiyaRBMhvV_3y1KXEO-Z6R9CYel-QoIcp2Y0uhyleB61isJt8q9ZAm_mm5H_mX47V9D1cO9g370jETgMAgAG5rqe815vEHsRPe86zljQ=&original_referer=&sessionRedirect=https%3A%2F%2Fwww.linkedin.com%2Fin%2Flawrence-platt (last visited Oct. 3, 2023).

[redacted] Ex. 144 (JJHCS_00000645)—[redacted]

While JJHCS asserts that her documents are likely captured by those of other custodians, discovery shows otherwise: (1) She attended a one-on-one with Kinne regarding SaveOnSP that, by definition, Franz did not, Ex. 81 (JJHCS_00008989); [redacted] Ex. 145 (JJHCS_00010064)—indicating that Wyszkowski worked on aspects of CarePath without Franz's direct involvement.

Burden & Proportionality

JJHCS has no valid argument that adding these individuals as custodians would be burdensome or disproportionate to the needs of this case.

First, JJHCS refused to quantify the burden of adding these twelve custodians, rebuffing SaveOnSP's requests that it provide hit counts of unique documents identified by its search terms. Ex. 6 (Aug. 28, 2023 Ltr.). JJHCS thus cannot meet its burden to show that adding the requested custodians would be unduly burdensome. *Steven Madden, Ltd. v. Jasmin Larian, LLC*, 2019 WL 3940112, at *2 (S.D.N.Y. July 8, 2019) (finding vague assertions that proposed custodians' document would be duplicative "unsupported by evidence and meritless"). JJHCS's burden claims would also not be credible: Putting aside its other divisions, J&J makes over $50 billion from specialty drug sales each year, including over $10 billion from Stelara and Tremfya alone. *2022 Annual Report*, JOHNSON & JOHNSON at 25 (Mar. 2023) https://www.investor.jnj.com/asm/2022-annual-report. It cannot seriously claim that, having chosen to bring this lawsuit, it lacks the resources to live up to its discovery obligations.

Second, JJHCS has no credible basis to argue that adding these custodians would be disproportionate to the needs of this case. JJHCS seeks over $100 million in damages—and climbing. Compl. ¶ 5. JJHCS has consistently maintained that it was proportionate and not unduly burdensome for SaveOnSP to review over 700,000 documents plus claims data and call records. If that is so, then JJHCS cannot be heard to assert that reviewing a smaller number of documents would somehow be out of proportion.

Finally, JJHCS's assertion that it is too late in the discovery process for it to add custodians, Ex. 7 at 1 (Sept. 11, 2023 Ltr.), is absurd. Discovery is open and will remain so under the current schedule until January 26, 2024. SaveOnSP added a custodian at JJHCS's request as recently as September 5, 2023. JJHCS also asked the Court to delay resolution of SaveOnSP's motions to compel until JJHCS completed its productions on key subjects, but JJHCS then withheld the vast majority of its current production until June 9, 2023, at which point SaveOnSP began identifying the individuals identified herein. Having stonewalled for months, JJHCS should not be able to use the discovery schedule as a basis to withhold these custodian's files.

SaveOnSP asks the Court to compel JJHCS to add the above twelve custodians and run all agreed-upon or Court-ordered search terms and any future agreed-upon or Court-ordered search terms over their files.

JJHCS's Position

JJHCS is the plaintiff here, and is among the many victims of SaveOnSP's misconduct. The record now confirms that SaveOnSP went to enormous lengths for years to cover its tracks and hide its existence from JJHCS and others in the pharmaceutical industry, so that its misappropriation of hundreds of millions of dollars in ***patient*** assistance money might go undetected for as long as possible. SaveOnSP sought to be, in its own words, [redacted] JJHCS Ex. 1 (SOSP_0391777). Therefore, it is not surprising that most of the relevant evidence is not in JJHCS's files, but rather in SaveOnSP's. Even so, JJHCS designated and timely produced discovery from seventeen document custodians, plus thousands of pages more from its central files. As SaveOnSP concedes above, JJHCS substantially completed its production nearly four months ago—in compliance with the original deadline, before SaveOnSP sought and obtained two lengthy delays in the discovery schedule.

This latest letter motion by SaveOnSP—its fifth such manifesto in recent weeks—must be viewed in this context. As detailed below, there is no merit whatsoever to SaveOnSP's accusations that it lacks critical discovery. Instead, what has become clear is that SaveOnSP is determined to keep delaying trial in this matter indefinitely. Having already obtained two extensions due to its own laggard efforts in producing documents, SaveOnSP now hopes to effectively restart the clock altogether, this time by demanding that JJHCS add twelve unnecessary custodians. This overbroad demand would force Janssen to expend enormous time and effort collecting and processing hundreds of thousands of documents for potential review and production. And that burden and delay is the whole point of SaveOnSP's motion. Indeed, SaveOnSP's true motive is evidenced by the fact that JJHCS first declined to add some of the disputed employees back in March—***more than seven months ago***. There was absolutely no reason for SaveOnSP to procrastinate bringing this dispute to the Court for more than half a year, other than to manufacture yet more delay, perhaps hoping that the Court will, at a minimum, split the baby and thereby reward SaveOnSP's extreme demands.[9]

Many of SaveOnSP's arguments above are simply retreads of those made in its previously briefed motions about, e.g., the Janssen Americas Leadership Team (the "JALT") (*see* Dkt. No. 122), the CAP program, and changes to the Stelara and Tremfya terms and conditions (*see* Dkt.

[9] SaveOnSP seeks to shift the blame for its own delay to JJHCS, claiming that JJHCS asked the Court to "delay resolution" of ***other*** discovery motions. *Supra* at 15. That is irrelevant and deeply misleading. The truth is that, until today, SaveOnSP never moved to compel the addition of any of these custodians, even though JJHCS promptly advised SaveOnSP of its position regarding some of them more than half a year ago. SaveOnSP has no one to blame but itself for the extreme untimeliness of this motion.

No 146). In an effort to reduce the burden on the Court, JJHCS does not repeat its responses to those arguments here. Suffice it to say that JJHCS has already designated custodians to provide all necessary coverage of these issues, including Katie Mazuk, a JALT member who is ***the*** senior-most executive with responsibility for making decisions about JJHCS's co-pay assistance programs. (*See* Dkt. No. 162.) JJHCS also already has agreed to expand its search terms—adding 32,000 additional documents on the CAP program during the meet and confer process on SaveOnSP's now pending motion. And as to the Stelara and Tremfya terms and conditions, JJHCS already has produced 1,700 documents, spanning over 17,800 pages, hitting on search terms designed to capture the topics in which SaveOnSP claims to be interested. (Dkt. No. 146 at 25.)

SaveOnSP's remaining arguments are without merit. *First*, SaveOnSP complains that it has produced more documents, in response to more document requests, than JJHCS has. At the outset, SaveOnSP's claim that JJHCS has reviewed only "~20,000" documents to date is patently false. But it is also beside the point. Again, the simple reason SaveOnSP has had to review and produce more documents than JJHCS is that this case is about SaveOnSP's conduct, not JJHCS's. It is therefore of no moment that SaveOnSP has produced many more documents concerning its conduct. In any event, just as JJHCS drafted and served 94 requests for production of documents over the last seventeen months, SaveOnSP could have chosen to do the same. So there is no basis for SaveOnSP's false equivalence, or its insistence that JJHCS must add more custodians just to review some untold additional number of documents.

Second, SaveOnSP draws the strange inference that additional JJHCS custodians are necessary because "the vast majority of its production—over 12,500 documents—came from only ***four*** custodians or from noncustodial files." *See supra* at 2. Of course, the files are what they are; JJHCS cannot control the volume of responsive materials within each custodian's email, hard drive, or text messages. If anything, this reflects simply that the relevant knowledge about SaveOnSP's operations was limited to a small number of people at JJHCS, which is not surprising given SaveOnSP's self-professed goal of operating in the shadows. Nor it is surprising that JJHCS has produced a high volume of "noncustodial" files, such as co-pay assistance claims data, budget information, and other data centrally stored on JJHCS's systems. Indeed, SaveOnSP has come to this Court repeatedly to ask for such information claiming that such data was "highly relevant," "crucial," and "critical" to SaveOnSP's defenses. (*E.g.*, Dkt. No. 150 (seeking to compel financial data).) SaveOnSP cannot now use those noncustodial productions to justify the need for twelve additional custodians.

Finally, for some reason SaveOnSP complains that JJHCS substantially completed its document production back in early June, many months before SaveOnSP did. This weighs strongly against SaveOnSP's application: by its own admission, SaveOnSP has had nearly five months with JJHCS's documents to raise any concerns. And whenever JJHCS has offered compromise proposals during that window, SaveOnSP has insisted on an all-or-nothing approach. It is time for the parties to move forward with this case, by proceeding to depositions and then to trial. SaveOnSP's motion to add twelve JJHCS custodians should be denied.

JJHCS Already Produced Relevant Materials from the JALT

SaveOnSP insists that three more members of the JALT should be added as custodians: Scott White, Blasine Penkowski, and Ernie Knewitz. None are likely to possess additional relevant materials sufficient to justify the burden of their late addition. The JALT is composed of high-level executives from across J&J's worldwide pharmaceutical business who set the direction for the entire business around the globe, including Katie Mazuk, who is both the senior executive in charge of CarePath and an existing JJHCS custodian. Ms. Mazuk—not Mr. White, Ms. Penkowski, or Mr. Knewitz—has principal responsibility for the CarePath co-pay assistance program, in her role as Vice President, Patient Engagement and Customer Solutions. JJHCS Ex. 2 (JJHCS_00001542). Any actions taken with respect to CarePath would be discussed by either Ms. Mazuk or people who report to her. In other words, SaveOnSP already has the documents it claims to need. *See Sugg v. Virtusa*, 2020 WL 6585872, at *2 (D.N.J. Nov. 10, 2020) (refusing to add two senior executives because existing custodians were already "top employees" and further discovery would be "duplicative"); *Lauris v. Novartis AG*, 2016 WL 7178602, at *4 (E.D. Cal. Dec. 8, 2016) (requiring "more than mere speculation to order [the producing party] to include the apex custodians in [a] search protocol").[10] JJHCS briefly addresses each JALT custodian in more detail below.

Blasine Penkowski. JJHCS objects to SaveOnSP's request to add Blasine Penkowski, JJHCS's Chief Strategic Customer Officer, as an additional custodian. SaveOnSP first raised Ms. Penkowski in the June 23, 2023 Joint Letter in support of its motion to expand the scope of discovery to companies besides JJHCS. As JJHCS explained at that time, JJHCS has "no reason to believe that Ms. Penkowski would have unique documents or communications relating to the SaveOnSP or JJHCS's response to the SaveOnSP program." (Dkt. No. 122 at 12.)

Nothing has changed since June. First, Ms. Penkowski's involvement with JALT is not relevant to this lawsuit and does not justify adding her as a custodian. As we have repeatedly explained to SaveOnSP, responsibility for the CarePath program resides principally with Katie Mazuk, Vice President, Patient Engagement and Customer Solutions ("PECS") and her reporting line. Ms. Mazuk is a member of JALT and an existing JJHCS custodian. As a result, any

[10] SaveOnSP argues above that "the apex doctrine can[not] be used categorically to avoid e-discovery of high-level executives." *Supra* at 3 n.2. That is a strawman. JJHCS has never argued that its executives can "categorically" avoid e-discovery, and indeed, JJHCS agreed the start of this matter to produce documents from such executives who actually have relevant responsibilities. The problem now is that SaveOnSP is seeking to harass executives whose documents would be cumulative of those JJHCS produced months ago. SaveOnSP's own cases recognize that under Rule 26 "a demand may not be cumulative, irrelevant to the resolution of the dispute, or disproportionate to the needs of the case." *Sandoz, Inc. v. United Therapeutics Corp.*, 2020 WL 13830525, at *3 (D.N.J. Nov. 16, 2020). There is no good reason to add Mr. White, Ms. Penkowski, and Mr. Knewitz—all senior executives—as custodians where Ms. Mazuk, another member of the JALT with direct responsibility for CarePath co-pay assistance already is a custodian and appears on the relevant JALT communications. *See, e.g.*, JJHCS Exs. 3-6 (JJHCS_00101570, JJHCS_00001668, JJHCS_00001830, and JJHCS_00101641).

communications to all members of JALT that reference CarePath copay assistance, SaveOnSP, or this litigation already are captured by Ms. Mazuk's documents. (Dkt. No. 122 at 9.) This is reflected in the JALT documents cited by SaveOnSP: Ms. Mazuk is included on all of them. *See* JJHCS Exs. 3-6 (JJHCS_00101570, JJHCS_00001668, JJHCS_00001830, and JJHCS_00101641).

Second, SaveOnSP's citation to a handful of non-JALT documents does not alter this conclusion. For example, SaveOnSP describes JJHCS_00084221 as an email [redacted]" *See supra* at 4. This is an inaccurate characterization of the document, which was sent to both Katie Mazuk and Heith Jeffcoat (two existing custodians) copying Ms. Penkowski. Notably, Ms. Penkowski is neither the sender, nor the sole receiver of this email, and more importantly, is not a participant in the discussion. Similarly, SaveOnSP claims that Ms. Penkowski [redacted]" but nothing in the document cited by SaveOnSP supports that claim. Rather, JJHCS_00101641 simply shows [redacted]

Third, SaveOnSP's citation to documents alleging that Ms. Penkowski has "unique information" about SaveOnSP or TrialCard similarly fall flat. Ms. Penkowski's receipt of a publicly available March 2022 report is not a reason to add her as a custodian. *See* JJHCS_00074697. Nor are Statements of Work between JJHCS and TrialCard. *See* JJHCS_00025908; JJHCS_00025517; JJHCS_00025532; JJHCS_00024511; JJHCS_00025594. SaveOnSP argues that because Ms. Penkowski signed these Statements of Work that she somehow has "unique information" about JJHCS's relationship with TrialCard. But that logic isn't borne out by the documents—nor is the nature of JJHCS's relationship with TrialCard central to the litigation.

Finally, none of the documents referenced in SaveOnSP's motion justifies discovery from apex personnel, i.e., high-level executives, like Ms. Penkowski. *See, e.g.*, *Lauris*, 2016 WL 7178602, at *4. "Mere speculation" that Ms. Penkowski's position as "a senior executive might increase the relevance of [her] files" is not a basis for designating her as a custodian. *Mortg. Resol. Servicing, LLC v. JPMorgan Chase Bank, N.A.*, 2017 WL 2305398, at *3 (S.D.N.Y. May 18, 2017). SaveOnSP offers no reason to believe that Ms. Penkowski would have unique documents or communications specific to SaveOnSP or JJHCS's response to the SaveOnSP program.

Scott White. Scott White is Company Group Chairman, North America Pharmaceuticals. He is among the highest ranking executives in the Johnson & Johnson family of companies with no day-to-day responsibilities for CarePath. (*See* Dkt. No. 122 at 12.) Mr. White is therefore entitled to protection from undue burden and harassment under the apex doctrine. *See Lauris*, 2016 WL 7178602, at *4; *Mortg. Resol. Servicing, LLC*, 2017 WL 2305398, at *3. Moreover, SaveOnSP's own cited documents show that relevant documents in Mr. White's possession related to JALT would be found in documents belonging to Ms. Mazuk, an existing custodian. *See, e.g.*,

JJHCS_00001704 ([redacted]); JJHCS_00011154 ([redacted]; JJHCS_00041213 ([redacted]); JJHCS_00001830 ([redacted], and JJHCS_00001668 ([redacted]). All of these documents clearly include Ms. Mazuk on the email chain.

SaveOnSP's claim that Mr. White is likely to have unique documents rests on gross distortions of the documents it cites. For example, SaveOnSP cites what it calls a "[redacted]" JJHCS_00100210, to suggest that such complaints make Mr. White a necessary custodian. But even a cursory review of that document demonstrates its irrelevance. It has nothing whatsoever to do with SaveOnSP or the issues in this action; instead, [redacted] Even setting that aside, Mr. White forwarded the complaint to the relevant JJHCS personnel, including John King, an already designated JJHCS custodian (which is why SaveOnSP has it). Again, SaveOnSP's stretch merely illustrates its lack of legitimate bases to add Mr. White as a custodian.

Finally, SaveOnSP's citation to various Statements of Work and change orders do not alter this view. *See* JHCS_00039767, JJHCS_00039772, JJHCS_00039696, JJHCS_00039374, JJHCS_00039378, JJHCS_00039382, JJHCS_00039625, and JJHCS_00039879. None indicate that Mr. White has "unique information" about JJHCS's relationship with TrialCard—and in any event, TrialCard is already producing documents pursuant to a subpoena served by SaveOnSP.

Ernie Knewitz. There is no basis to add Ernie Knewitz, a Janssen Vice President of Communications, as an additional custodian. Based on its investigations to date, JJHCS has no reason to believe that Mr. Knewitz would have unique documents relating to SaveOnSP or JJHCS's response to the SaveOnSP program. As JJHCS explained in its July 28, 2023 Supplemental Responses and Objections to SaveOnSP's First Set of Interrogatories, Mr. Knewitz was [redacted] JJHCS Ex. 7 (JJHCS's July 28, 2023 Supplemental Responses & Objections to SaveOnSP's First Set of Interrogatories). To the extent Mr. Knewitz has documents relating to this Action, those would be protected by the attorney-client privilege or work product doctrine.

In addition, Mr. Knewitz's involvement with JALT does not merit his addition as a custodian. As JJHCS has made clear, responsibility for the CarePath program resides principally with Katie Mazuk, Vice President, Patient Engagement and Customer Solutions and her reporting line. Ms. Mazuk is a member of JALT and an existing JJHCS custodian. Any JALT communications that reference CarePath co-pay assistance, SaveOnSP, or this litigation, already are captured by Ms. Mazuk's documents. (*See* Dkt. No. 122 at 9.) This is reflected in the documents cited by SaveOnSP. *See* JJHCS_00001857 ([redacted], JJHCS_00041213 ([redacted]); JJHCS_00083266 ([redacted]

[redacted]). Notably, even in these irrelevant discussions, Mr. Knewitz is neither the sender, nor the sole receiver of this email, and more importantly, is not a participant in either discussion.

Finally, SaveOnSP again relies on JJHCS_00001704 to state that because Mr. Knewitz received a copy of the SaveOnSP presentation video, he is relevant to this litigation. That is a nonstarter for the reasons discussed above.

SaveOnSP Has Not Justified Its Demand to Add Irrelevant Brand Employees

SaveOnSP insists that JJHCS add two additional "brand" custodians for certain immunology and oncology drugs: Karen Lade and Juliette Deshaies. *See supra* at 6-7. To be clear, when SaveOnSP says these are "brand" employees, it means they do not work on or make decisions regarding patient co-pay assistance programs, and instead work on issues relating to the sales and marketing of drugs. Moreover, JJHCS already has added several custodians specific to each of these therapeutic areas. For immunology, JJHCS has produced documents from four custodians: Spilios Asimakopoulos, Lauren Pennington, Lindsey Anderson, and Jasmeet Singh. Two other custodians, Lynn Hall and Silviya McCool, are specific to oncology. SaveOnSP has given no good reason why JJHCS must add additional custodians for specific drugs—an absurd request, given that SaveOnSP has targeted at least ***eighteen*** Janssen drugs in its scheme. JJHCS briefly discusses each requested employee in more detail below.

Karen Lade. Since SaveOnSP first requested Karen Lade more than four months ago, JJHCS has been clear that it has no reason to believe Ms. Lade—a Product Director of Rheumatology Marketing at Janssen Pharmaceuticals—would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. To the extent Ms. Lade's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other agreed-upon custodians, including Heith Jeffcoat, Silviya McCool, Lauren Pennington, and Spilios Asimakopoulos. This is confirmed by several documents cited by SaveOnSP such as JJHCS_00002688, JJHCS_00045468, JJHCS_00083180, JJHCS_00083183, JJHCS_00083894, JJHCS_00083929, JJHCS_00083931, and JJHCS_00105296 which contain correspondence between Ms. Lade and current agreed-upon custodians. At most, SaveOnSP has demonstrated that Ms. Lade provided some information to JJHCS personnel who did work on CarePath, and their emails have already been produced.

Remarkably, SaveOnSP tries to argue otherwise by relying exclusively on documents from a three-month window in 2016—many years before JJHCS became aware of SaveOnSP's existence, and indeed before SaveOnSP claimed its operations even began. Not a single cited document post-dates September 2016. And the documents are not only old, they are also utterly irrelevant. For example, SaveOnSP cites an August 2016 chain in which Spilios Asimakopoulos (already a JJHCS custodian) asked a second employee, Howard Reid, for [redacted] JJHCS Ex. 8 (JJHCS_00083183). [redacted]

[redacted] *See id.* The same is true for JJHCS_00105296. [redacted] *Id.* (emphasis removed); *see also* JJHCS_00083929- JJHCS_00083932 ([redacted]). And none of these documents even discuss CarePath's co-pay assistance program, further demonstrating that there is no principled reason to force Ms. Lade's addition as a custodian.

Juliette Deshaies. SaveOnSP also has not justified its ask to add Juliette Deshaies as a custodian. Indeed, SaveOnSP's own description of Ms. Deshaies's role, and the documents it cites, make clear that Ms. Deshaies's primary responsibilities relate to marketing of certain immunology drugs—not CarePath or any other issues relevant to this action. For example, in JJHCS_0069842, [redacted] *See id.*

This is completely consistent with JJHCS's prior representations—[redacted] *See id.* Again, to the extent Ms. Deshaies's custodial files contain relevant documents or communications, they would be cumulative of those documents JJHCS has produced from other agreed-upon custodians, including Spilios Asimakopoulos, Heith Jeffcoat, Lynn Hall, and Adrienne Minecci.

SaveOnSP's reliance on JJHCS_00083836 is similarly misplaced. [redacted] *See* JJHCS_00083836.

The same is true for JJHCS_00083826, which includes Ms. Hall and Ms. McCool (both custodians). And contrary to SaveOnSP's mischaracterization, that document does not [redacted] Again, SaveOnSP's practice of mischaracterizing JJHCS's documents is revealing: if SaveOnSP's application had any merit, SaveOnSP would not need to rewrite the record to support it.

SaveOnSP's remaining citations are not to the contrary. To be clear, Ms. Deshaies was not involved in setting the terms and conditions, nor does JJHCS_00059501 support such a view. Nor did Ms. Deshaies "overs[ee] the CarePath program for Simponi Aria." *See* JJHCS_00114605. Taken together, the remaining documents show that Ms. Deshaies had some involvement or participation in website development (JJHCS_00059500) and brochures (JJHCS_00061959; JJHCS_00061961; JJHCS_00011144) alongside others, including Adrienne Minecci and Lynn Hall (both existing custodians). Accordingly, there is no reason to add Ms. Deshaies as a custodian at this late juncture.

JJHCS Already Has Agreed to Produce Documents Relevant to CAP

SaveOnSP insists that JJHCS add seven additional custodians who are purportedly relevant to efforts by JJHCS to identify patients who have been subjected to "accumulator" or "maximizer" programs by their insurers: Quinton Kinne, Daphne Longbothum, William Shontz, Allison Barklage, John Hoffman, L.D. Platt, and Leigh Wyszkowski. *See supra* at 7-14. But JJHCS already has agreed to review 32,000 additional documents hitting on search terms tied to these cost or co-pay adjustment program ("CAP") efforts—and additional discovery related to CAP is the subject a separate SaveOnSP motion. SaveOnSP's motion as to these additional seven custodians should be denied: none are likely to possess additional relevant materials to justify the burden of their late addition and JJHCS already has agreed to produce documents relevant to CAP.

Quinton Kinne. SaveOnSP has known since March that JJHCS would not agree to add Quinton Kinne as a custodian, because he is unlikely to have unique, responsive documents, and therefore should not be added as a custodian. SaveOnSP first proposed Mr. Kinne as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 and July 28, 2023 letters. SaveOnSP yet again seeks his addition, relying on a near verbatim argument, a handful of previously cited documents, and interrogatory responses that SaveOnSP has had for ten months.

These documents remain unpersuasive to justify adding Mr. Kinne as an additional custodian. For example, the email chain that SaveOnSP seeks in JJHCS_00035757 will be captured by other designated JJHCS custodians, including Lindsey Anderson and Bill Robinson, who are specifically mentioned in the document cited by SaveOnSP. JJHCS Ex. 9 (*See* July 28, 2023 Ltr. from J. Long to E. Snow at 2.) [redacted] *See* JJHCS_00010098. Non-privileged, responsive communications related to that work would be captured by Mr. Franz's documents. And even if it were true that Mr. Kinne [redacted] it does not follow that he has unique and relevant documents in his exclusive possession. *See* JJHCS_00008989.

To the extent that Mr. Kinne participated in internal analyses or calls related to the CAP program, he did so alongside JJHCS existing custodians, including Heith Jeffcoat. *See* JJHCS_00135344 ([redacted]; JJHCS_00135351 ([redacted]). And while SaveOnSP argues that "JJHCS

appears to have produced relevant documents from his files," SaveOnSP omits that the handful of relevant files were all spreadsheets—they provide zero reason to go sifting through Mr. Kinne's emails, as SaveOnSP proposes to do. The bottom line, once again, is that SaveOnSP already has the relevant documents.

Daphne Longbothum. Daphne Longbothum also is unlikely to have unique, responsive documents, and therefore should not be added as a custodian. SaveOnSP first proposed Ms. Longbothum as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 and July 28, 2023 letters and informed SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Ms. Longbothum would have unique documents or communications relating to SaveOnSP" and that her documents would be cumulative of "other custodians from whom JJHCS has agreed to produce documents, including Nidhi Saxena and Hattie McKelvey, to whom Ms. Longbothum reported." JJHCS Ex. 9 (July 28, 2023 Ltr. from J. Long to E. Snow at 3 (quoting May 19, 2023 Ltr. from H. Sandick to E. Snow at 2)).

None of the materials cited in SaveOnSP's August 28 letter change that conclusion. SaveOnSP cites to Daphne Longbothum [redacted] but fails to recognize Nidhi Saxena, a current JJHCS custodian and Ms. Longbothum's supervisor, *see* JJHCS_00000027, received the same communication. *See* JJHCS_00008591. The other documents cited by SaveOnSP are similarly unpersuasive. For example, as JJHCS explained in its July 28, 2023 letter, SaveOnSP's reliance on JJHCS_00001391 is peculiar because Ms. Longbothum is neither the sender nor the sole receiver of this emails and, more importantly, is not involved in the discussion. In fact, JJHCS_00001391 is a conversation between Nidhi Saxena and Jeremy Mann—two JJHCS custodians—with others, including Ms. Longbothum, copied.

SaveOnSP claims that Ms. Longbothum is nonetheless "likely to have unique documents" because Ms. Longbothum allegedly [redacted] but then cites to documents received by both Nidhi Saxena and Jeremy Mann (both custodians), *see* JJHCS_00001464, emails directed at JJHCS listservs which include Nidhi Saxena, *see* JJHCS_00008838, or emails where Ms. Longbothum twice copies Nidhi Saxena back onto a chain, *see* JJHCS_00008802 ([redacted]). These documents do not support adding Ms. Longbothum as yet another custodian.

William Shontz. Similarly, there is no basis to add William Shontz as a custodian. SaveOnSP first proposed Mr. Shontz as a custodian on May 9, 2023. As JJHCS has repeatedly stated since that time, "JJHCS has no reason to believe that Mr. Shontz would have unique documents or communications relevant to the litigation, or that any such documents would not be cumulative of those produced from existing JJHCS custodians, Hattie McKelvey and Silviya McCool, to whom he reports." JJHCS Ex. 9 (July 28, 2023 Ltr. from J. Long to E. Snow at 3).

None of the documents cited by SaveOnSP merit adding Mr. Shonz. As previously stated, to the extent Mr. Shontz was involved in relevant communications, those documents would be captured by existing JJHCS custodians. [redacted]

[redacted] *See* JJHCS_00104645. In addition, SaveOnSP's reliance on JJHCS_00001202 to state that while Ms. McCool was out of office for four days, she briefly "directed people to reach out to Shontz," is insufficient to add him as an additional custodian. A four-day absence falls woefully short as a justification to add Mr. Shontz as a custodian. [redacted] JJHCS_00029708. Furthermore, SaveOnSP's reliance on JJHCS_00008556 and JJHCS_00034500 is odd because Mr. Shontz is neither the sender nor the sole receiver of these emails and did not participate in the discussion.

Alison Barklage. As JJHCS has repeatedly informed SaveOnSP, based on its investigation to-date, JJHCS understands that Ms. Barklage served as a JJHCS contractor during the relevant period with administrative responsibilities. Yet SaveOnSP continues to press for her addition, again citing [redacted] *See* JJHCS_00084174. Generating an actions items list does not transform Ms. Barklage's role, nor do the handful of tasks assigned to her. *See id.*

In addition, SaveOnSP's reliance on a series of cites to emails from Heith Jeffcoat to Ms. Barklage purportedly [redacted] does not move the needle. First, none of the cited emails include an ask for feedback on such presentations. *See* JJHCS_00084504; JJHCS_00084426; JJHCS_00084507. Second, at least one of these decks was already "presented" at the time it was sent to Ms. Barklage. *See* JJHCS_00084426. Consistent with JJHCS's July 28 letter, to the extent Ms. Barklage's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other agreed-upon custodians, including, *inter alia*, Heith Jeffcoat, to whom Ms. Barklage reported.

Nor are SaveOnSP's new citations to the contrary. SaveOnSP relies on Ms. Barklage being the "only sender of an email to [Mr.] Jeffcoat regarding a presentation." *See supra* at 12. But JJHCS_00084681 supports JJHCS's description of Ms. Barklage's role: [redacted] *See* JJHCS_00069174.

John Hoffman. Similarly, there is no basis to add John Hoffman as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Mr. Hoffman would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. SaveOnSP's reliance on JJHCS_00027236, JJHCS_00026852, and JJHCS_00101570 are not to the contrary. Mr. Hoffman is neither the sender, nor the sole receiver of these emails, and more importantly, is not involved in the discussion.

To the extent Mr. Hoffman's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other agreed-upon custodians, including John King and Silas Martin. [redacted] *See* JJHCS_00133499 ([redacted]; JJHCS_00133495 ([redacted]).

L.D. Platt. L.D. Platt works in public affairs, and JJHCS has no reason to believe that Mr. Platt would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. As JJHCS explained in its July 28, 2023 Supplemental Responses and Objections to SaveOnSP's First Set of Interrogatories, Mr. Platt [redacted] JJHCS Ex. 7 (JJHCS's July 28, 2023 Supplemental Responses & Objections to SaveOnSP's First Set of Interrogatories). To the extent Mr. Platt has documents relating to this Action, those would be protected by the attorney-client privilege, work product doctrine, or another applicable privilege or protection from disclosure. *See* JJHCS_00027974, JJHCS_00027996. In addition, Mr. Platt is neither the sender, nor the sole receiver of these emails, and more importantly, is not a participant in the discussion.

[redacted] JJHCS Ex. 7 (JJHCS's July 28, 2023 Supplemental Responses & Objections to SaveOnSP's First Set of Interrogatories).

Leigh Wyszkowski. This is another inexcusably late demand. SaveOnSP first proposed Ms. Wyszkowski as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 and July 28, 2023 letters and informed SaveOnSP that Ms. Wyszkowski's documents and communications "will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Wyszkowski reported." *See* July 28 Ltr. from J. Long to E. Snow at 2 (quoting May 19, 2023 Ltr. from H. Sandick to E. Snow at 4).

Nothing has changed in the last seven months. For example, SaveOnSP asserts that because Leigh Wyszkowski [redacted], *see* JJHCS_00000551, Ms. Wyszkowski is relevant to this litigation. By that logic, anyone who received or read the Complaint would be a potential discovery target, since the Complaint cites this presentation. This is untenable. As JJHCS has repeatedly stated, Mr. Kinne and Ms. Wyszkowski are in the same reporting line and all responsive documents would be captured by John Paul Franz's documents. Indeed, this is consistent with the documents that SaveOnSP cites. In JJHCS_00008989, for example, a JJHCS custodian appears at both the beginning and the end of the chain. Ms. Wyszkowski did not even participate in the discussion.

* * *

For the foregoing reasons, there is no basis to add any of the twelve custodians SaveOnSP has belatedly demanded. The Court should deny SaveOnSP's motion and this matter should proceed to depositions and trial without further delay.

* * *

The parties appreciate the Court's attention to this matter.

Respectfully submitted,

/s/ *E. Evans Wohlforth, Jr.*
E. Evans Wohlforth, Jr.
Robinson & Cole LLP
666 Third Avenue, 20th floor
New York, NY 10017-4132
Main (212) 451-2900
Fax (212) 451-2999
ewohlforth@rc.com

David Elsberg (admitted *pro hac vice*)
Andrew R. Dunlap (admitted *pro hac vice*)
Meredith Nelson (admitted *pro hac vice*)
Elizabeth H. Snow (admitted *pro hac vice*)
SELENDY GAY ELSBERG PLLC
1290 Avenue of the Americas
New York, NY 10104
(212) 390-9000
deslberg@selendygay.com
adunlap@selendygay.com
mnelson@selendygay.com
esnow@selendygay.com

Attorneys for Defendant Save On SP, LLC

/s/ *Jeffrey J. Greenbaum*
Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

Adeel A. Mangi
Harry Sandick (admitted *pro hac vice*)
George LoBiondo
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff Johnson & Johnson Health Care Systems Inc.

Exhibit 1

Patterson Belknap

www.pbwt.com

February 6, 2023

Harry Sandick
(212) 336-2723
hsandick@pbwt.com

VIA EMAIL

Andrew Dunlap, Esq.
Selendy Gay Elsberg PLLC
1290 Avenue of the Americas
New York, NY 10104
adunlap@selendygay.com

Re: JJHCS's Proposed Custodians and Search Methodology
Johnson & Johnson Health Care Systems Inc. v. Save On SP, LLC, No. 22 Civ. 2632 (JMV) (CLW)

Dear Andrew:

As agreed during our meet and confer on January 30, 2023, we write to provide JJHCS's proposed custodians and search methodology for its production of documents in response to SaveOnSP's Requests for Production, subject to the limitations and objections set forth in JJHCS's responses.

For each of SaveOnSP's requests where JJHCS has agreed to search for and produce documents, Appendix A identifies whether JJHCS plans to search custodial or non-custodial sources. As to the requests for which JJHCS plans to search custodial files, JJHCS's proposed custodians are Spilios Asimakopolous, John Paul Franz, Heith Jeffcoat, Jeremy Mann, Katie Mazuk, Silviya McCool, Hattie McKelvey, Lauren Pennington, Bill Robinson, Nidhi Saxena, and Jasmeet Singh. JJHCS reserves the right to revise and narrow these custodians if SaveOnSP fails to identify and produce from a corresponding number of document custodians.

Appendix B lists the search terms and date ranges JJHCS proposes to use to identify responsive documents from its custodians for purposes of document review. We reserve the right to modify these search terms, or our anticipated document custodians, with notice to you, if the search terms and custodians in combination return unacceptably high rates of false hits or generate a volume that would constitute undue burden to review and produce.

Very truly yours,

Harry Sandick

Appendix A

Req #	Custodial or Non-Custodial
1	Non-custodial
4	Non-custodial
5	Non-custodial
8	Custodial & non-custodial
12	Non-custodial
13	Non-custodial
14	Custodial
25	Custodial & non-custodial
27	Non-custodial
28	Non-custodial
29	Non-custodial
31	Custodial
35	Non-custodial
36	Non-custodial
42	Custodial
45	Non-custodial

Appendix B

Search Terms	Date Range
(STELARA* OR TREMFYA* OR CarePath OR JCP OR "Savings Program") w/25 (6000 OR 6,000 OR limit OR eliminate)	January 1, 2020 to July 1, 2022
SaveOnSP OR SaveOn OR "Save On SP" OR "Save OnSP"	January 1, 2017 to July 1, 2022
"essential health benefit*" OR EHB* OR "non-essential health benefit" OR "nonessential health benefit*" OR NEHB*	January 1, 2017 to July 1, 2022
("Express Scripts" OR ESI) w/50 (accumulat* OR maximiz*)	January 1, 2017 to July 1, 2022
(essential OR nonessential OR non-essential OR "non essential") w/50 ("Affordable Care Act" OR ACA OR Obamacare)	January 1, 2017 to July 1, 2022
Accredo w/50 (accumulat* OR maximiz*)	January 1, 2017 to July 1, 2022
"Save On"[1]	January 1, 2017 to July 1, 2022
"save on" w/50 (accumulat* OR maximiz* OR "essential health benefit*" OR EHB* OR "non-essential health benefit*" OR "nonessential health benefit*" OR NEHB* OR accredo OR ESI OR "express scripts")	January 1, 2017 to July 1, 2022

[1] For this search term only, JJHCS will employ a case-sensitive search mechanism.

Exhibit 2

Patterson Belknap

www.pbwt.com

March 16, 2023

Harry Sandick
(212) 336-2723
hsandick@pbwt.com

VIA EMAIL

Andrew Dunlap, Esq.
Selendy Gay Elsberg PLLC
1290 Avenue of the Americas
New York, NY 10104
adunlap@selendygay.com

Re: JJHCS's Proposed Search Methodology
Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC,
No. 22 Civ. 2632 (ES) (CLW)

Dear Andrew:

We write in response to your March 7, 2023 letter regarding JJHCS's proposed custodians and search methodology for its production of documents in response to SaveOnSP's Requests for Production.

I. JJHCS's Proposed Custodians

JJHCS designated 11 custodians. SaveOnSP requests that JJHCS add an additional 23 custodians.

JJHCS agrees to add Lynn Hall, John King, Adrienne Minecci, Heather Schoenly, Carol Scholz as additional custodians.

JJHCS declines to add Jennifer De Camara, Harman Grossman, and Savaria Harris as custodians. All three individuals are attorneys and are not proper custodians in this matter, as any relevant documents or communications would be protected by the attorney-client privilege, work product doctrine, or another applicable privilege or protection from disclosure.

JJHCS declines to add Laura Bohorquez Perez as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Perez would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Katie Mazuk, to whom Ms. Perez reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Chad Bower as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Mr. Bower would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John King, to whom Mr. Bower reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Rhonda Burden as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Burden would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Burden reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Stacy Cashman as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Cashman would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Katie Mazuk and John King, to whom Ms. Cashman reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Diane DeLoria as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. DeLoria would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John King, to whom Ms. DeLoria reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Jeffrey Doherty as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Mr. Doherty would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John King, to whom Mr. Doherty reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period

can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Gina Giordano as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Giordano would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John King, to whom Ms. Giordano reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Stephanie Hoch as a custodian. JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath. Further, to the extent JJHCS does produce documents or communications related to the marketing of CarePath, any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Adrienne Minecci, to whom Ms. Hoch reported.

JJHCS declines to add Brad Katz as a custodian. Documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath, and to the extent JJHCS does produce documents or communications related to the marketing of CarePath, any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Adrienne Minecci, to whom Mr. Katz reported.

JJHCS declines to add Quinton Kinne as a custodian. Documents or communications relating to Mr. Kinne's work with counsel would be protected by the attorney-client privilege, work product doctrine, or another applicable privilege or protection from disclosure. Further, any relevant documents or communications not covered by such privileges or protections will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Mr. Kinne reported.

JJHCS declines to add Renee Shiota as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Shiota would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John King, to whom Ms. Shiota reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Maura Snyder as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Ms. Snyder would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Katie Mazuk, to whom Ms. Snyder reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Jeff Vernice as a custodian. Based on its investigation to date, JJHCS has no reason to believe that Mr. Vernice would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program, and any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Hattie McKelvey and John King, to whom Mr. Vernice reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time period can be produced from non-custodial sources. Further, JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath.

JJHCS declines to add Leigh Wyszkowski as a custodian. Any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Wyszkowski reported. In addition, documents sufficient to show CarePath's budget and costs for the relevant time.

JJHCS declines to add Daniel Xavier as a custodian. JJHCS has not agreed or otherwise been ordered to produce documents or communications related to the marketing of CarePath. Further, to the extent JJHCS does produce documents or communications related to the marketing of CarePath, any relevant documents or communications will be captured by other custodians from whom JJHCS has agreed to produce documents, including Adrienne Minecci, to whom Mr. Xavier reported.

II. JJHCS's Proposed Search Terms

SaveOnSP has proposed several revisions and additions to JJHCS's search terms. JJHCS is willing to make the following additions, shown in redline, to the search terms proposed in JJHCS's February 6 letter for the January 1, 2017 to July 1, 2022 time period:

- SaveOnSP OR SaveOn OR "Save On SP" OR "Save OnSP" OR Save-On OR SOSP OR "Jody Miller" OR "Ron Krawczyk"
- ("Express Scripts" OR ESI OR ExpressScripts) w/50 (accumulat* OR maximiz*)
- (Accredo OR Acredo) w/50 (accumulat* OR maximiz*)

JJHCS also agrees to run the following search term requested by SaveOnSP for the January 1, 2017 to July 1, 2022 time period:

- "essential health benefit*" OR EHB* OR "non-essential health benefit" OR "nonessential health benefit*" OR NEHB*

The remainder of SaveOnSP's proposed revisions and additions to JJHCS's search terms are inappropriate. SaveOnSP requests a date range of January 1, 2009 to July 1, 2022 for most of its terms, but JJHCS has not agreed to produce documents for that time period, nor has it been ordered to do so. Further, SaveOnSP has not identified which RFPs it is targeting with its proposed terms, but the remainder of SaveOnSP's proposed terms appear to be aimed at capturing categories of documents that JJHCS has not agreed to or otherwise been ordered to produce, including documents relating to CarePath's marketing and Janssen drug prices.

III. JJHCS's Proposed Document Sources

SaveOnSP objects to JJHCS's use of exclusively non-custodial sources for RFP Nos. 12 and 13. In its February 17 letter, JJHCS agreed to produce "internal documents and communications relating to the drafting of CarePath's terms and conditions during the relevant time period of January 1, 2017 to July 1, 2022, to the extent such non-privileged documents exist and can be identified after a reasonable search." Feb. 17 Ltr. at 2. Further, in its February 24 letter, JJHCS agreed to "conduct a reasonable search for non-privileged documents and communications during the relevant time period of January 1, 2017 to July 1, 2022 bearing on the meaning of the 'other offer' provision at issue in this case." Feb. 23 Ltr. at 2. Accordingly, JJHCS agrees to run the following two search terms for the January 1, 2017 to July 1, 2022 time period:

- "other offer" W/5 (accumulat* OR maximiz* OR "health plan*" OR insur*)
- "This program offer may not be used with any other coupon, discount, prescription savings card, free trial, or other offer"

SaveOnSP also objects to JJHCS's use of exclusively non-custodial sources for RFP No. 27. SaveOnSP requests "all Documents and Communications regarding the 'internal JJHCS data' discussed in Complaint ¶¶ 92-101, including the complete databases from which that data was drawn." RFP No. 27. JJHCS, however, agreed to produce only "the data that formed the basis for the allegations in Complaint ¶¶ 92-100." R&O to RFP No. 27. Production of that data can be accomplished via non-custodial sources. Therefore, JJHCS will not produce documents from custodial sources for RFP No. 27.

Further, SaveOnSP objects to JJHCS's use of exclusively non-custodial sources for RFP No. 29. SaveOnSP requests "[f]rom January 1, 2009 through the present, for each Janssen Drug for each year, all Documents and Communications regarding" a variety of categories relating to CarePath's budget and revenues generated by Janssen drugs. RFP No. 29. JJHCS, however, agreed to produce only "non-privileged documents in its possession for the relevant Time Period

sufficient to show (1) how JJHCS determines the amounts of copay assistance funds that JJHCS offers to Patients enrolled in CarePath, (2) JJHCS's budget for copay assistance through CarePath, and (3) JJHCS's actual and projected annual costs for CarePath, to the extent such documents exist and can be located after a reasonable search." R&O to RFP No. 29. Production of those documents can be accomplished via non-custodial sources. Therefore, JJHCS will not produce documents from custodial sources for RFP No. 29.

Finally, SaveOnSP objects to "JJHCS's apparent refusal to search any sources in response to RFPs not listed on its Appendix A" and states that it "understand[s] that JJHCS's apparent refusal to conduct these searches is based on its objections to SaveOnSP's RFPs, and that it will modify Appendix A to reflect agreements reached by the parties or orders issued by the Court." To the extent JJHCS agrees or is otherwise ordered to produce additional documents, it will update its Appendix A. To that end, Appendix A attached includes updates to reflect the agreements that JJHCS has made to date.

* * *

Best regards,

Harry Sandick

Appendix A

Req #	Custodial or Non-Custodial
1	Non-custodial
4	Non-custodial
5	Non-custodial
8	Custodial & non-custodial
12	Custodial & non-custodial
13	Custodial & non-custodial
14	Custodial
20	Custodial & non-custodial
25	Custodial & non-custodial
27	Non-custodial
28	Non-custodial
29	Non-custodial
31	Custodial
35	Non-custodial
36	Non-custodial
42	Custodial
45	Non-custodial

Exhibit 3

Patterson Belknap

www.pbwt.com

July 17, 2023

Harry Sandick
(212) 336-2723
hsandick@pbwt.com

Andrew Dunlap, Esq.
Selendy Gay Elsberg PLLC
1290 Avenue of the Americas
New York, NY 10104

Re: Supplemental Interrogatory Responses
Johnson & Johnson Health Care Systems Inc. v. Save On SP, LLC,
No. 22 Civ. 2632 (ES) (CLW)

Dear Andrew:

We write in response to your July 5, 2023 letter regarding the Court's June 29, 2023 Order directing JJHCS to conduct a further investigation and supplement its responses to SaveOnSP's First Set of Interrogatories, as appropriate.

The Court's June 29, 2023 Order is clear: it directs JJHCS to "conduct a further investigation regarding non-JJHCS personnel (e.g., employees of Janssen entities) responsible for making decisions regarding the CarePath program," and to "supplement its interrogatory responses, as appropriate." (Dkt. No. 127.) For the avoidance of doubt, JJHCS will fully comply with the Court's Order and intends to supplement its responses to SaveOnSP's First Set of Interrogatories in the near future.

JJHCS will not, however, agree to the additional requirements that SaveOnSP attempts to unilaterally impose on JJHCS and that are wholly outside the Court's June 29 Order. In your July 5, 2023 letter, you stated that the Court's Order "require[s] JJHCS to identify individuals . . . with knowledge of or involvement with decisions over the topics in SaveOnSP's Interrogatories. This is not limited to actual decision-makers, but includes those who reviewed, commented, advised, provided input, or assisted with those decisions." July 5, 2023 Ltr. from A. Dunlap to H. Sandick. This misstates both the language of SaveOnSP's First Set of Interrogatories and the Court's directive. SaveOnSP's Interrogatory Nos. 1 to 7 all rely on the same language: "Identify each person who participated in or had responsibility for . . ." a specific topic. *See, e.g.*, SaveOnSP's First Set of Interrogatories at 12. Nothing in the Court's Order expands that language to the broader set of persons suggested in your July 5 letter.

SaveOnSP also attempts to expand JJHCS's obligations to topics not covered by SaveOnSP's First Set of Interrogatories. This is inappropriate. JJHCS declines to agree to this expanded scope. To be clear, the Court's June 29 Order did not extend the language of SaveOnSP's First Set of Interrogatories. (*See* Dkt. No. 127.) Rather, the Court directed JJHCS to "conduct a further investigation" and to "supplement its interrogatory responses, as appropriate."

(*Id.*) This is consistent with the Court's directive at the June 27 conference that JJHCS must "[d]o the investigation" and "[a]nswer the interrogatories." June 27, 2023 Hr'g Trans. at 99:10–11.

Finally, in your July 5 letter, SaveOnSP conveys its understanding concerning the scope of any "reasonable investigation" to include "at a minimum, all members of the Janssen Americas Leadership Team and their support staffs, including communications teams" as well as "Janssen Drug brand employees who are likely to interact with CarePath." July 5, 2023 Ltr. from A. Dunlap to H. Sandick, at 2. JJHCS disagrees. Consistent with the Court's June 29 Order, JJHCS will undertake a further investigation regarding non-JJHCS personnel who may be responsible for making decisions regarding the CarePath program and will supplement its interrogatory responses, as appropriate. (*See* Dkt. No. 127.)

Very truly yours,

/s/ Harry Sandick
Harry Sandick

Exhibit 4

July 28, 2023

Julia Haigney Long
(212) 336-2878

VIA EMAIL

Elizabeth H. Snow, Esq.
Selendy Gay Elsberg, PLLC
1290 Avenue of the Americas
New York, NY 10104

Re: *Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC*
No. 2:22-cv-02632 (ES) (CLW)

Dear Elizabeth:

We write in response to your July 18, 2023 letter concerning organizational charts, custodians, and search terms.

I. Organizational Charts

A. Time Period

SaveOnSP asks for "organizational charts covering the full time period from April 1, 2016 through December 1, 2016." July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 1. To the extent any such relevant organizational charts exist, JJHCS agrees to produce them.

B. Juliette Deshaies

In your July 18 letter, SaveOnSP acknowledges that JJHCS has twice confirmed that Juliette Deshaies is an employee of JJHCS. Nevertheless, SaveOnSP continues to ask for "all organizational charts on which [Juliette Deshaies] appears, whether from JJHCS or Janssen." *Id.* For the avoidance of any doubt, Ms. Deshaies is a JJHCS—not "Janssen"—employee. To the extent that Ms. Deshaies worked in a department at JJHCS that was responsible for CarePath co-pay assistance, those organization charts already have been produced. JJHCS will not produce organizational charts from JJHCS departments without responsibility for the CarePath co-pay assistance program.

C. Groups in JJHCS's Organizational Charts

In your July 18 letter, SaveOnSP asks JJHCS to "explain the function" of fourteen groups named in JJHCS's organizational charts and to "provide the names of all members of each group, whether employed [by] JJHCS, at Janssen, or elsewhere in the J&J organization." *Id.* at 1-2. JJHCS declines. We are happy to work with you on good faith questions about the document

production process, but correspondence is not a forum for free-standing discovery beyond that permitted by the Federal Rules. Moreover, rather than a good faith effort to facilitate discovery, your query appears to be part of an ongoing and transparent attempt to restart the discovery clock *after* JJHCS named 17 custodians, produced thousands of documents, and was prepared to certify substantial completion.

II. Custodians

SaveOnSP asks JJHCS to "explain the function of the SMOX team and provide the names of all its members, whether employed at JJHCS or Janssen or elsewhere in the other J&J entities." *Id.* SMOX stands for "Supplier Management and Operational Excellence," and its team, which consists of 22 JJHCS employees, is tasked with supply-related adherence and compliance at JJHCS. John Paul Franz leads the SMOX team. To the extent that SMOX members worked on any relevant issues, we have produced those documents. Further discovery regarding SMOX is irrelevant.

As to individuals, JJHCS is prepared to add Quinton Kinne and Daphe Longbothum as custodians, subject to (1) those additions resolving this dispute about custodians and (2) SaveOnSP agreeing to add Ms. Ayesha Zulqarnain as an additional SaveOnSP custodian per our recent request. Absent such agreement, for the reasons discussed below, JJHCS declines to add the requested custodians.

A. Quinton Kinne

SaveOnSP first proposed Mr. Kinne as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 letter. SaveOnSP now again seeks his addition. The documents relied upon by SaveOnSP are unpersuasive to justify adding Mr. Kinne as an additional custodian. The email chain that SaveOnSP seeks in JJHCS_00035757 will be captured by other custodians from whom JJHCS has agreed to produce documents, including Lindsey Anderson, who is specifically mentioned in the document cited by SaveOnSP. July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 3. Nonetheless, given your repeated requests and in the interests of compromise, we are willing to add Mr. Kinne on the terms detailed above.

B. Leigh Wyszkowski

JJHCS declines to add Leigh Wyszkowski as an additional custodian. SaveOnSP first proposed Ms. Wyszkowski as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 letter and informed SaveOnSP that Ms. Wyszkowski's documents and communications "will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Wyszkowski reported." March 16, 2023 Ltr. from H. Sandick to A. Dunlap at 4. SaveOnSP now makes the exact same request when nothing has changed in the last four months. In addition, SaveOnSP's reliance on JJHCS_00008989 is misplaced. Even if Mr. Kinne had "one-on-one meetings" with Ms. Wyszkowski, it does not follow that those meetings would have generated relevant email traffic. As JJHCS has repeatedly stated, Mr. Kinne and Ms. Wyszkowski are in the same reporting line and all responsive documents

would be captured by John Paul Franz's documents. Moreover, as noted above, we have now offered to add Mr. Kinne.

C. Daphne Longbothum

SaveOnSP first proposed Ms. Longbothum as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 letter and informed SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Ms. Longbothum would have unique documents or communications relating to SaveOnSP" and that her documents would be cumulative of "other custodians from whom JJHCS has agreed to produce documents, including Nidhi Saxena and Hattie McKelvey, to whom Ms. Longbothum reported." May 19, 2023 Ltr. from H. Sandick to E. Snow at 2. SaveOnSP asks again, relying on the fact that "Ms. Longbothum's documents are not coextensive with Saxena's and McKelvey's documents" because they do not appear on three emails that Ms. Longbothum received. July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 3-4. SaveOnSP's reliance on JJHCS_00001393 and JJHCS_00034500 is peculiar. Ms. Longbothum is neither the sender, nor the sole receiver of these emails and, more importantly, is not involved in the discussion. Similarly, in JJHCS_00034526 is an email from Ms. Longbothum to Adrienne Minecci, an agreed-upon custodian. Any relevant part of that conversation would be captured by Ms. Minecci's documents or communications. Nonetheless, given your repeated requests and in the interests of compromise, we are willing to add Ms. Longbothum on the terms detailed above.

D. William Shontz

JJHCS declines to add William Shontz as an additional custodian. SaveOnSP first proposed Mr. Shontz as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 letter and its June 23, 2023 joint letter informing SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Mr. Shontz would have unique documents or communications relevant to the litigation, or that any such documents would not be cumulative of those produced from existing JJHCS custodians, Hattie McKelvey and Silviya McCool, to whom he reports." June 23, 2023 Joint Letter at 11. SaveOnSP asks again, claiming that Mr. Shontz's "documents are not completely captured by McKelvey or McCool." None of those documents merit adding Mr. Shonz. For example, SaveOnSP's reliance on JJHCS_00001202 to state that [redacted] is insufficient to add him as an additional custodian. [redacted] JJHCS_00001202 at 3. A four-day gap in coverage is hardly a reason to justify adding Mr. Shontz as a custodian. Furthermore, SaveOnSP's reliance on JJHCS_00008556, JJHCS_00034500, and JJHCS_00034531 is peculiar. Mr. Shontz is neither the sender, nor the sole receiver of these emails and, more importantly, is not involved in the discussion. This is wholly insufficient to add Mr. Shontz as an additional custodian.

E. Alison Barklage

JJHCS declines to add Alison Barklage as an additional custodian. Based on its investigation to date, Ms. Barklage served as a JJHCS contractor during the relevant period with administrative responsibilities. To the extent Ms. Barklage's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other

agreed-upon custodians, including Heith Jeffcoat, to whom Ms. Barklage reported, and Quinton Kinne, with whom Ms. Barklage worked.

III. Search Terms

JJHCS declines to add the search strings proposed by SaveOnSP in its July 18 letter. SaveOnSP has failed to propose any narrow supplemental search terms designed to search for particular documents. As such, we can only assume that these demands are intended to impose burden rather than a good faith effort to yield relevant discovery. As a threshold matter, two of SaveOnSP's proposed search strings containing the term "co-ins*" were too expansive to even be run in our database. JJHCS understands that when a modifier like "!" or "*" is used, the term can only be run if it generates less than 2,000 unique word hits. "Co-ins*" returned too many unique words to be run. In an effort to approximate SaveOnSP's requests, JJHCS has replaced that term with "co-insur*" in the chart below.

A typographical error in a third search string also prevented JJHCS from running the string: (CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay or payment or contrib*)) pay* w/100 (patient w/10 ("high deduc*) OR "high-deduc* OR "health savings" OR HSA). Again, in an effort to approximate SaveOnSP's requests, JJHCS has run this term as two strings "(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay or payment or contrib*))" and "pay* w/100 (patient w/10 ("high deduc*) OR "high-deduc* OR "health savings" OR HSA)."

JJHCS also declines to add these search strings based on the unduly burdensome number of additional unique documents hitting on these terms for the April 1, 2016 to July 1, 2022 time period. As summarized in the chart below, these nine terms would require JJHCS to review 296,475 unique documents including families—before adding either Quinton Kinne or Daphne Longbothum as custodians. At this stage in the litigation, this wholesale re-opening of discovery is simply unwarranted. We therefore decline to agree to these additional search terms.

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
CAP OR CAPm OR CAPa	86,548	181,765

[1] These hit counts exclude documents that have already been reviewed in the course of this litigation.

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay OR payment OR contrib*))	32,385	112,425
(Accredo OR Acredo) w/50 (accumulat* OR maximiz* OR copay* OR co-pay* OR coins* OR co-insur* OR "cost share")	4,087	8,883
Copay w/5 max*	3,685	20,573
copay assistance w/10 program	3,359	20,616
Copay w/5 accumulat*	3,337	10,592
("Express Scripts" OR ESI OR ExpressScripts) w/50 (accumulat* OR maximiz* OR copay* OR co-pay* OR coins* OR co-insur* OR "cost share")	2,140	10,594

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") w/100 (ACA OR "Affordable Care Act" OR Obamacare)	1,268	4,806
pay* w/100 (patient w/10 ("high deduc* OR" high-deduc* OR "health savings" OR HSA))	819	2,673

Very truly yours,

/s/ Julia Haigney Long
Julia Haigney Long

Exhibit 5

From: Elizabeth Snow
To: SaveOn-Team
Subject: FW: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)
Date: Wednesday, August 23, 2023 1:40:03 PM

Elizabeth Snow
Associate [Email]
Selendy Gay Elsberg PLLC [Web]
Pronouns: she, her, hers

+1 212.390.9330 [O]
+1 540.409.7257 [M]

From: Arrow, Sara (x2031) <sarrow@pbwt.com>
Sent: Wednesday, August 23, 2023 1:32 PM
To: Elizabeth Snow <esnow@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; David Elsberg <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Elizabeth—

Thank you for confirming that SaveOnSP will add Ms. Zulqarnain as a custodian. As requested in our July 25 letter, we expect you will prioritize production of her documents, as well as those of Jill Stearns and Jenna Ordonez.

Contrary to your suggestion, we do not agree that Quinton Kinne and Daphne Longbothum are necessary or appropriate custodians in this matter. Our position on this has been consistent since SaveOnSP first raised these individuals, going back to March for Mr. Kinne. We offered to add them solely in the interest of compromise and to resolve our disputes as to all of the requested custodians referenced in SaveOnSP's July 18 letter and as discussed during our meet and confer. We understand that SaveOnSP has chosen to reject that compromise and so we will not add Mr. Kinne or Ms. Longbothum.

Regards,
Sara

Sara A. Arrow
She | Her | Hers

Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com | www.pbwt.com

From: Elizabeth Snow <esnow@selendygay.com>
Sent: Tuesday, August 22, 2023 4:03 PM
To: Arrow, Sara (x2031) <sarrow@pbwt.com>; Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Sara,

We have considered your proposal, but do not agree. We will agree to add Ms. Zulqarnain as a custodian. We maintain that Mr. Kinne and Ms. Longbothum are relevant custodians likely to possess unique responsive documents, as evidenced, in part, by your agreement to add them in the first place. However, we will not withdraw our requests for other custodians who also appear likely to possess unique relevant documents. Please let us know promptly if you will agree to add Mr. Kinne and Ms. Longbothum without any such limitation.

Thanks,

Elizabeth

Elizabeth Snow
Associate [Email]
Selendy Gay Elsberg PLLC [Web]
Pronouns: she, her, hers
+1 212.390.9330 [O]
+1 540.409.7257 [M]

From: Arrow, Sara (x2031) <sarrow@pbwt.com>

Sent: Tuesday, August 22, 2023 8:46 AM
To: Elizabeth Snow <esnow@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; David Elsberg <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Elizabeth—

Please provide an update on the request below concerning custodians as soon as possible.

Thanks,
Sara

Sara A. Arrow
She | Her | Hers
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com | www.pbwt.com

From: Arrow, Sara (x2031)
Sent: Wednesday, August 16, 2023 6:09 PM
To: 'Elizabeth Snow' <esnow@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Elizabeth,

Thank you for confirming that you will begin these productions promptly. We must, however, insist that you complete these productions by the substantial completion deadline so that we can embark on depositions. Given your prior representations to the Court concerning the manner in which Messrs. Miller and Krawczyk use their personal email addresses, we are certain that you will be able to complete the productions by September 24.

As you'll recall from our letter of July 28 and our meet and confer of August 9, JJHCS was prepared to add Quinton Kinne and Daphne Longbothum as custodians, subject to (1) *those additions resolving the parties' dispute about custodians* and (2) SaveOnSP agreeing to add Ayesha Zulqarnain as an additional SaveOnSP custodian. *See* July 28, 2023 Letter from J. Long to E. Snow. Please confirm that our dispute as to Leigh Wyszkowski, William Shontz, Alison Barklage, and Juliette Deshaies is now resolved, and you will not seek to add them as custodians. Subject to that confirmation, we will add Mr. Kinne and Ms. Longbothum in exchange for the addition of Ms. Zulqarnain.

Regards,
Sara

Sara A. Arrow
She | Her | Hers
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com I www.pbwt.com

From: Elizabeth Snow <esnow@selendygay.com>
Sent: Wednesday, August 16, 2023 4:30 PM
To: Arrow, Sara (x2031) <sarrow@pbwt.com>; Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Caution: External Email!

Sara,

We will begin rolling productions of relevant emails from Jody Miller's and Ron Krawczyk's personal email addresses as promptly as we are able and will try to complete those productions by the current substantial completion discovery deadline.

We agree to the proposed trade on Ayesha Zulqarnain for Quinton Kinne and Daphne Longbothum's custodial files. As part of this, we will agree to search Ms. Zulqarnain's personal email account for

relevant emails. Please promptly confirm your agreement.

Thanks,

Elizabeth

Elizabeth Snow
Associate [Email]
Selendy Gay Elsberg PLLC [Web]
Pronouns: she, her, hers
+1 212.390.9330 [O]
+1 540.409.7257 [M]

From: Arrow, Sara (x2031) <sarrow@pbwt.com>
Sent: Wednesday, August 16, 2023 12:43 PM
To: Meredith Nelson <mnelson@selendygay.com>; Andrew Dunlap <adunlap@selendygay.com>; David Elsberg <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>; Elizabeth Snow <esnow@selendygay.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Counsel:

As you are aware, the Court issued an order this morning compelling production of relevant emails from Jody Miller's and Ron Krawczyk's personal email addresses. Please promptly let us know when we can expect your production of these documents.

In addition, it has now been over three weeks since we requested that you add Ayesha Zulqarnain as a custodian and prioritize production of her documents. We expect your prompt response, and if we do not receive it by Friday, August 18, we will proceed to motion practice on this issue. Further, in light of this morning's ruling, we fully expect that any production of Ms. Zulqarnain's documents will include a production from her personal email account(s) in addition to her SaveOnSP account. Please confirm the same.

Regards,

Sara

Sara A. Arrow
She | Her | Hers
Patterson Belknap Webb & Tyler LLP

1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com | www.pbwt.com

From: Meredith Nelson <mnelson@selendygay.com>
Sent: Thursday, August 10, 2023 11:10 AM
To: Arrow, Sara (x2031) <sarrow@pbwt.com>; Andrew Dunlap <adunlap@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>; Elizabeth Snow <esnow@selendygay.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Caution: External Email!

Sara,

As we told you during yesterday's meet and confer, we are actively investigating Ms. Zulquarnain's involvement in matters relevant to this litigation and are collecting her documents so we can evaluate the burden associated with your request. Once we have completed our investigation, we will respond to your request. We will aim to do so by Friday, but it may take until next week.

Regards,

Meredith

Meredith Nelson
Associate [Email]
Selendy Gay Elsberg PLLC [Web]
Pronouns: she, her, hers
+1 212.390.9069 [O]
+1 918.200.3148 [M]

From: Arrow, Sara (x2031) <sarrow@pbwt.com>
Sent: Wednesday, August 9, 2023 7:30 PM
To: Andrew Dunlap <adunlap@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; David Elsberg <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>; Elizabeth

Snow <esnow@selendygay.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Counsel:

Please let us know when we can expect a response to the request in our July 25, 2023 letter to add Ayesha Zulqarnain as a custodian. Please provide a substantive response on or before August 11, 2023. In the event that we do not receive a substantive response by August 11, we will conclude that we are at impasse on this issue.

In the event that you do not agree to add Ms. Zulqarnain as a custodian, consistent with your representation during our meet and confer today, we expect that you will provide a hit count, including for both Ms. Zulqarnain's SaveOnSP and her personal Gmail address.

Regards,
Sara

Sara A. Arrow
She | Her | Hers
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com | www.pbwt.com

From: Arrow, Sara (x2031)
Sent: Tuesday, July 25, 2023 12:44 PM
To: Andrew Dunlap <adunlap@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>; 'Elizabeth Snow' <esnow@selendygay.com>
Cc: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>; Brisson, Katherine (x2552) <kbrisson@pbwt.com>; Shane, Beth (x2659) <eshane@pbwt.com>
Subject: RE: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Counsel,

Please see the attached.

Regards,
Sara

Sara A. Arrow
She | Her | Hers
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
Phone: (212) 336-2031
Fax: (212) 336-2092
sarrow@pbwt.com | www.pbwt.com

From: Elizabeth Snow <esnow@selendygay.com>
Sent: Friday, July 21, 2023 7:35 PM
To: LoBiondo, George (x2008) <globiondo@pbwt.com>; Mangi, Adeel A. (x2563) <aamangi@pbwt.com>; Sandick, Harry (x2723) <hsandick@pbwt.com>; Arrow, Sara (x2031) <sarrow@pbwt.com>; Haigney Long, Julia (x2878) <jhaigneylong@pbwt.com>; ~jgreenbaum@sillscummis.com <jgreenbaum@sillscummis.com>; ~klieb@sillscummis.com <klieb@sillscummis.com>
Cc: Andrew Dunlap <adunlap@selendygay.com>; Meredith Nelson <mnelson@selendygay.com>; ~delsberg@selendygay.com <delsberg@selendygay.com>; Wohlforth, E. Evans <EWohlforth@rc.com>
Subject: JJHCS v. SaveOnSP (Case No. 2:22-cv-02632-ES-CLW)

Caution: External Email!

Counsel,

Please find attached two letters in the above-captioned matter. The link to access the production is: https://www.dropbox.com/sh/4znlkdafnu7304w/AABSWNhRdS6rkvDtaAOpG-NEa?dl=0.

A password will follow under separate cover.

Best,

Elizabeth

Elizabeth Snow
Associate [Email]
Selendy Gay Elsberg PLLC [Web]
Pronouns: she, her, hers

+1 212.390.9330 [O]

+1 540.409.7257 [M]

Privileged/Confidential Information may be contained in this message. If you are not the addressee indicated in this message (or responsible for delivery of the message to such person), you may not copy or deliver this message to anyone. In such case, you should destroy this message and kindly notify the sender by reply email. Please advise immediately if you or your employer do not consent to receiving email messages of this kind.

Privileged/Confidential Information may be contained in this message. If you are not the addressee indicated in this message (or responsible for delivery of the message to such person), you may not copy or deliver this message to anyone. In such case, you should destroy this message and kindly notify the sender by reply email. Please advise immediately if you or your employer do not consent to receiving email messages of this kind.

Privileged/Confidential Information may be contained in this message. If you are not the addressee indicated in this message (or responsible for delivery of the message to such person), you may not copy or deliver this message to anyone. In such case, you should destroy this message and kindly notify the sender by reply email. Please advise immediately if you or your employer do not consent to receiving email messages of this kind.

Exhibit 6

Selendy Gay Elsberg PLLC
1290 Avenue of the Americas
New York NY 10104
212.390.9000

Elizabeth Snow
Associate
212 390 9330
esnow@selendygay.com

August 28, 2023

Via E-mail

Julia Haigney Long
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036
jhaigneylong@pbwt.com

Re: *Johnson & Johnson Health Care Systems Inc. v. Save On SP, LLC* (Case No. 2:22-cv-02632-JMV-CLW)

Dear Julia,

SaveOnSP writes to ask that JJHCS add the individuals identified below as custodians. Some requests are new; others follow up on prior requests.

If JJHCS objects to adding any individual on the ground that doing so would be unduly burdensome or that their documents would be duplicative or cumulative of those of another custodian, please provide hit counts of how many unique, relevant documents would be identified for that individual by each of the terms that JJHCS has agreed to run or that SaveOnSP has moved the Court for it to run on its existing custodians. *See Steven Madden, Ltd. v. Jasmin Larian, LLC*, 2019 WL 3940112, at *2 (S.D.N.Y. July 8, 2019) (finding vague assertions that proposed custodians' document would be duplicative "unsupported by evidence and meritless").

A. Quinton Kinne

SaveOnSP asks that JJHCS add Quinton Kinne as a custodian. SaveOnSP first made this request in its March 7, 2023 letter. In its July 28, 2023 letter, JJHCS offered to add Kinne as a custodian if SaveOnSP would add Ayesha Zulqarnain and drop all other requests for other custodians; SaveOnSP added Zulquarnain but did not agree to forego all other custodian requests.

Kinne is relevant to this litigation: (1) JJHCS identified Mr. Kinne as

[redacted]

[redacted] Jan. 17, 2023 JJHCS's Resps. to SaveOnSP's First Interrogatories at 15-16; [redacted].

Kinne is likely to have unique documents. In its March 16, 203 letter, JJHCS argued that Kinne's documents would be captured by John Paul Franz's documents. In its July 28, 2023 letter, JJHCS claimed that Kinne's documents would be captured by Lindsey Anderson's documents. Discovery has shown otherwise: [redacted]—indicating that he has unique documents regarding JJHCS's responses to SaveOnSP.

B. Daphne Longbothum

SaveOnSP asks that JJHCS add Daphne Longbothum as a custodian. SaveOnSP first made this request in its May 9, 2023 letter. In its July 28, 2023 letter, JJHCS offered to add Longbothum as a custodian if SaveOnSP would add Ayesha Zulqarnain and drop all other requests for other custodians; SaveOnSP added Zulquarnain but did not agree to forego all other custodian requests.

Longbothum is relevant to this litigation: (1) she is the Manager, Patient Affordability & Access Solutions, Pulmonary Hypertension, for the Janssen Pharmaceutical Companies of Johnson & Johnson, Daphne Longbothum, LINKEDIN, https://www.linkedin.com/in/daphne-longbothumb734862b (last visited Aug. 27, 2023); ([redacted]

Longbothum is likely to have unique documents. In its May 19, 2023 letter, JJHCS asserted that all her relevant documents would be captured by Nidhi Saxena's and Hattie McKelvey's documents. In its July 28, 2023 letter, JJHCS asserted that her documents would be captured by Adrienne Minecci's documents. Discovery has shown otherwise: [redacted]

C. Juliette Deshaies

SaveOnSP asks that JJHCS add Juliette Deshaies as a custodian. SaveOnSP first made this request in its May 9, 2023 letter.

Deshaies is relevant to this litigation. Per LinkedIn, she was the Group Product Director of the ERLEADA Patient Experience. Juliette Deshaies, LINKEDIN, https://www.linkedin.com/in/juliette-deshaies-1132b44 (last visited May 9, 2023). As JJHCS represented to the Court, Deshaies worked on the marketing of multiple Janssen Drugs at issue, June 23, 2023 Joint Ltr. at 11, ECF No. 127 (Deshaies's "primary responsibilities related to the marketing of Simponi Aria, Stelara, and Tremfya").

While JJHCS asserted that Deshaies's "primary responsibilities" did not include CarePath, *id.*, discovery shows that Deshaies was heavily involved with that program: [redacted]

[redacted]

Deshaies is likely to have unique documents. In its May 19, 2023 letter, JJHCS asserts that her documents would be cumulative of those in the files of custodians Spilios Asimakopoulos, Heith Jeffcoat, and Lynn Hall. Discovery shows otherwise: [redacted]

D. Leigh Wyszkowski

SaveOnSP asks that JJHCS add Leigh Wyszkowski as a custodian. SaveOnSP first made this request in its March 7, 2023 letter.

Wyszkowski is relevant to this litigation: (1) she is the Director of Fee for Service (FFS) Execution & Cut Supplier Management as part of the Strategic Customer Groups, JJHCS_00000346; [redacted]

Wyszkowski is likely to have unique documents. In its March 16, 2023 letter, JJHCS asserted that her communications would be captured by other custodians, including Franz. Discovery shows otherwise: [redacted]

E. William Shontz

SaveOnSP asks that JJHCS add William Shontz as a custodian. SaveOnSP first made this request in its May 9, 2023 letter.

Shontz is relevant to this litigation. Per LinkedIn, he is Associate Director, Patient Access and Affordability Solutions, Oncology at Johnson & Johnson. William (Will) Shontz, LINKEDIN, https://www.linkedin.com/in/williamtshontz (last visited May 9, 2023). Shontz worked on the marketing of CarePath. [redacted]

Shontz worked on setting CarePath's budget and modifying its terms and conditions: [redacted]

[redacted]

Shontz is likely to have unique documents. In its May 19, 2023 letter, JJHCS claimed that his documents and communications would be captured by the documents of custodians Nidhi Saxena and Hattie McKelvey. In the June 23, 2023 joint letter, JJHCS asserted that his documents would be captured by the documents of custodians McKelvey and Silviya McCool. Discovery shows otherwise: [redacted]

[redacted]

F. Alison Barklage

SaveOnSP asks that JJHCS add Alison Barklage as a custodian. SaveOnSP first made this request in its July 18, 2023 letter.

Barklage is relevant to this litigation. While JJHCS asserted in its July 28, 2023 letter that she was a "JJHCS contractor during the relevant period with administrative responsibilities," LinkedIn states that from 2004 to 2007 she was a Consulting Director at Johnson & Johnson and from 2011 to the present has been the President of AKB Consulting (her own company), in which she "delivers change & project management consulting for large pharmaceutical companies" and "support[s] senior stakeholders with project management on critical business initiatives, including issue identification, stakeholder engagement & communications, project planning, dashboard status reporting, and success measurement plans."[1]

Discovery confirms that her work for JJHCS was substantive: [redacted]

[1] Alison Barklage, MHSA, LINKEDIN, https://www.linkedin.com/in/alison-barklage?challengeId=AQFbgDDvMikQdAAAAYotJLka16VvfLHioohPKqHkyHQq8-x8kcseu4DpAyvTdJVIQsr0EHO_irv6te5zBl4ZpmiokUGq-gnyfw&submissionId=a11fb285-55a7-7e17-f8f8-22be33e1a736&challengeSource=AgEdBx4PytP1swAAAYotJO8HtPee3A-dt2H1mjjKjMQQi7fuI_H-PqNqfXcY7m8&challegeType=AgEEI2s1TqMI3QAAAYotJO8LI_gIY5uJ0J4qMy9wQdzaZGx4qhGD2YI&memberId=AgGbLaHzLoTyeAAAAYotJO8OUy_dh7q02DhaOAmyeVtVWiY&recognizeDevice=AgFf9b5VuiQntgAAAYotJO8SLSPSWYD0Dv5BdP2y1X2lUqTey2kg (last visited Aug. 25, 2023).

[redacted]

Barklage is likely to have unique documents. In its July 28, 2023 letter, JJHCS asserted that her files would be captured by Jeffcoat's documents. Discovery shows otherwise: [redacted]

G. Blasine Penkowski

SaveOnSP requests that JJHCS add Ms. Penkowski as a custodian.

Penkowski is relevant to this litigation: (1) she serves as the Chief Strategic Customer Officer of JJHCS,[2] *see* JJHCS_00000106; [redacted]

[2] In the June 23, 2023 joint letter, JJHCS indicated that Penkowski and Scott White were immune from discovery under the apex doctrine. In fact, "the 'apex doctrine,' while it may be applicable to depositions, is not a protective shield that prohibits document discovery from high-ranking executives." *Sandoz, Inc. v. United Therapeutics Corp.*, 2020 WL 13830525, at *3 (D.N.J. Nov. 16, 2020) (citing *Nat'l Labor Relations Bd v. 710 Long Ridge Rd Operating Co. II, LLC*, 2020 WL3026523 at *2 (D.N.J. June 5, 2020)).

[redacted]

Penkowski is likely to have unique documents. In the June 23, 2023 joint letter, JJHCS asserted that her files would be captured by those belonging to Katie Mazuk. Discovery shows otherwise: [redacted]

H. Scott White

SaveOnSP requests that JJHCS add Mr. White as a custodian.

White is relevant to this litigation: (1) he is a member of JALT and serves as the Company Group Chairman for North America Pharmaceuticals Johnson & Johnson, *see* JJHCS_00001542; [redacted]

White is likely to have unique documents. In its June 23, 2023 joint letter, JJHCS asserted that his files would be captured by Mazuk's documents. Discovery

shows otherwise: [redacted]

I. Karen Lade

SaveOnSP requests that JJHCS add Karen Lade as a custodian.

Lade is relevant to this litigation. She appears to be a Product Director, Integrated Customer Solution, Patient Affordability Strategy at Janssen Immunology,[3] JJHCS_00002688. [redacted]

Lade is likely to have unique documents. In the June 23, 2023 joint letter, JJHCS asserted that she was not likely to have unique documents because she simply provided information about CarePath to other JJHCS personnel. Discovery shows otherwise: [redacted]

J. L.D. Platt

SaveOnSP asks that JJHCS add L.D. Platt as a custodian. He is relevant to this litigation: (1) JJHCS identified him as an individual who [redacted] July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories at 12, [redacted]

[3] Ms. Lade does not appear on any organizational chart produced to date by JJHCS.

[redacted]

K. Ernie Knewitz

SaveOnSP asks that JJHCS add Ernie Knewitz as a custodian. He is relevant to this litigation: (1) JJHCS identified him as an individual who [redacted] July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories at 12; [redacted]

L. Silas Martin

SaveOnSP asks that JJHCS add Silas Martin as a custodian. He is relevant to this litigation: (1) JJHCS identified him as a person who [redacted] July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories at 23-24; [redacted]

M. John Hoffman

SaveOnSP asks that JJHCS add John Hoffman as a custodian. He is relevant to this litigation: (1) JJHCS identified him as a person who [redacted] July 28, 2023 JJHCS Suppl. Resps. to SaveOnSP's First Interrogatories at 23-24; (2) per LinkedIn, as the former head of Health Policy & Advocacy at Johnson & Johnson, he "help[ed] to enact state legislation prohibiting non-medical switching and copay accumulator and maximizer programs";[4] and [redacted]

* * *

We request a response by September 5, 2023.

We reserve all rights and are available to meet and confer.

Best,

/s/ Elizabeth Snow

Elizabeth H. Snow
Associate

---

[4] John Hoffman, LINKEDIN, https://www.linkedin.com/in/john-hoffman-b788147?challengeId=AQHIg4eOVl86lAAAAYovUZQ9SsGyvdo2HYtutCig6Xv1wLmAESYejIZNNUm5tj_f3xXdkNRIsO2pKckOxXoyNv2iDuWS_CHTJA&submissionId=80ad3273-86c8-7e17-a1fe-77f347742717&challengeSource=AgH1X6LAia67HwAAAYovU4AHBhdazZxe-czPqZAJoV210KYm5wu7ZSjcwBLBnKw&challegeType=AgGRK-8FFEdBJgAAAYovU4AJHwvS8UwxYtNjfsJqMYjqd1mPyaC3LvM&memberId=AgGo7hRMgBgeJAAAAYovU4AMGQyolcdLCH7f9bLEylRddVo&recognizeDevice=AgGseyLBagE6qAAAAYovU4APYASa3jZyEgK90MKG0BoiwT_PF69U (last visited Aug. 25, 2023)

Exhibit 7

September 11, 2023

Julia Long
(212) 336-2878

VIA EMAIL

Elizabeth H. Snow, Esq.
Selendy Gay Elsberg, PLLC
1290 Avenue of the Americas
New York, NY 10104

Re: ***Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC***
No. 2:22-cv-02632 (ES) (CLW)

Dear Elizabeth:

We write in response to your August 28, 2023 letter demanding that JJHCS add thirteen more custodians.

At the outset, it must be said that SaveOnSP has not proceeded in good faith with respect to the issue of custodians. We met and conferred over several hours on August 8 and 9 related to various discovery issues and were scheduled to discuss six of the thirteen requested custodians during that meet and confer. Yet SaveOnSP refused to confer about its own request for these custodians until JJHCS provided a hit count—despite not asking for such a count in advance of our meet-and-confer. SaveOnSP also refused to discuss JJHCS's then-pending offer to withdraw its relevance and burden objections as to two custodians (Quinton Kinne and Daphne Longbothum) "subject to (1) those additions resolving this dispute about custodians and (2) SaveOnSP agreeing to add Ms. Ayesha Zulqarnain as an additional SaveOnSP custodian[.]" July 28, 2023 Ltr. from J. Long to E. Snow at 1. Following the August 8 and 9 meet and confers, JJHCS renewed this offer—and SaveOnSP again declined to accept the two-for-one custodian deal and doubled down on its requests to add four additional custodians.

Instead of negotiating in good faith or asking JJHCS to consider targeted additional custodians, SaveOnSP now demands that JJHCS add thirteen new custodians—mere weeks before the substantial completion deadline, and half a year after SaveOnSP first raised and then dropped several of the demands at issue. This appears to be part of SaveOnSP's ongoing and transparent campaign to restart the discovery clock. JJHCS timely produced thousands of documents from 17 custodians, and has substantially completed its discovery obligations on the Court's original schedule. And so, with one partial exception described in more detail below, JJHCS declines to add the requested individuals or to provide hit counts of their documents, which would require the full collection, processing, and analysis of thirteen custodians at this late stage. This burdensome exercise is not proportionate or merited given SaveOnSP's unwillingness to proceed in good faith and narrow or tailor its sweeping demands.

I. Custodians Addressed in Prior Correspondence

JJHCS declines to add Quinton Kinne, Daphne Longbothum, Juliette Deshaies, Leigh Wyszkowski, Willian Shontz and Alison Barklage as additional custodians. As JJHCS has stated since SaveOnSP first raised this issue, these individuals are irrelevant to this litigation and the documents relied upon by SaveOnSP do not justify adding them as additional custodians.

A. Quinton Kinne

JJHCS declines to add Quinton Kinne as an additional custodian. SaveOnSP first proposed Mr. Kinne as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 and July 28, 2023 letters. SaveOnSP yet again seeks his addition, relying on a near verbatim argument, a handful of previously cited documents, and interrogatory responses that SaveOnSP has had for nearly eight months.

These documents remain unpersuasive to justify adding Mr. Kinne as an additional custodian. For example, the email chain that SaveOnSP seeks in JJHCS_00035757 will be captured by other designated JJHCS custodians, including Lindsey Anderson and Bill Robinson, who are specifically mentioned in the document cited by SaveOnSP. *See* July 28 Ltr. from J. Long to E. Snow at 2. [redacted] *See* JJHCS_00010098. Non-privileged, responsive communications related to that work would be captured by Mr. Franz's documents. And even if it were true that [redacted]

B. Daphne Longbothum

JJHCS declines to add Daphne Longbothum as an additional custodian. SaveOnSP first proposed Ms. Longbothum as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 and July 28, 2023 letters and informed SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Ms. Longbothum would have unique documents or communications relating to SaveOnSP" and that her documents would be cumulative of "other custodians from whom JJHCS has agreed to produce documents, including Nidhi Saxena and Hattie McKelvey, to whom Ms. Longbothum reported." *See* July 28 Ltr. from J. Long to E. Snow at 3 (quoting May 19, 2023 Ltr. from H. Sandick to E. Snow at 2).

None of the materials cited in SaveOnSP's August 28 letter change that conclusion. [redacted] *See* JJHCS_00008591. The other documents cited by SaveOnSP are similarly unpersuasive. For example, as JJHCS explained in its July 28, 2023 letter, SaveOnSP's reliance on JJHCS_00001391 and JJHCS_00034500 is peculiar because Ms. Longbothum is neither the sender nor the sole receiver of these emails and, more importantly, is not involved in the discussion. In fact,

JJHCS_00001391 is a conversation between Nidhi Saxena and Jeremy Mann—two JJHCS custodians—with others, including Ms. Longbothum, copied.

SaveOnSP claims that Ms. Longbothum is nonetheless "likely to have unique documents" because [redacted] These documents do not support adding Ms. Longbothum as yet another custodian.

C. Leigh Wyszkowski

JJHCS declines to add Leigh Wyszkowski as an additional custodian. SaveOnSP first proposed Ms. Wyszkowski as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 and July 28, 2023 letters and informed SaveOnSP that Ms. Wyszkowski's documents and communications "will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Wyszkowski reported." *See* July 28 Ltr. from J. Long to E. Snow at 2 (quoting May 19, 2023 Ltr. from H. Sandick to E. Snow at 4).

Nothing has changed in the last four months. For example, SaveOnSP asserts that because [redacted] Leigh Wyszkowski is relevant to this litigation. By that logic, anyone who received or read the Complaint would be a potential discovery target, since the Complaint cites this presentation. This is untenable. As JJHCS has repeatedly stated, Mr. Kinne and Ms. Wyszkowski are in the same reporting line and all responsive documents would be captured by John Paul Franz's documents.

D. William Shontz

JJHCS declines to add William Shontz as an additional custodian. SaveOnSP first proposed Mr. Shontz as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 and July 28, 2023 letters. As JJHCS has repeatedly stated, "JJHCS has no reason to believe that Mr. Shontz would have unique documents or communications relevant to the litigation, or that any such documents would not be cumulative of those produced from existing JJHCS custodians, Hattie McKelvey and Silviya McCool, to whom he reports." *See* July 28 Ltr. from J. Long to E. Snow at 3.

None of the documents cited by SaveOnSP merit adding Mr. Shonz. As previously stated, to the extent Mr. Shontz was involved in relevant communications, those documents would be captured by existing JJHCS custodians. For example, SaveOnSP cites communications [redacted]

f[redacted]

E. Alison Barklage

JJHCS declines to add Alison Barklage as an additional custodian. As JJHCS stated in its July 28 letter, we understand that Ms. Barklage served as a JJHCS contractor during the relevant period with administrative responsibilities. Yet SaveOnSP now relies on a [redacted]. *See* JJHCS_00084174. Generating an actions items list does not transform Ms. Barklage's role, nor do the handful of tasks assigned to her. *See id.*

In addition, SaveOnSP's reliance on a series of cites to emails [redacted]

F. Juliette Deshaies

JJHCS also declines to add Juliette Deshaies as a custodian. As JJHCS stated in its May 19 letter, SaveOnSP's own description of Ms. Deshaies's role, and the documents it cites, make clear that Ms. Deshaies's primary responsibilities relate to marketing of certain immunology drugs—not CarePath or any other issues relevant to this action. [redacted]

This is completely consistent with JJHCS's prior representations—[redacted] *See id.* Again, to the extent Ms. Deshaies's custodial files contain relevant documents or communications, they would be cumulative of those documents JJHCS has produced from other agreed-upon custodians, including Spilios Asimakopoulos, Heith Jeffcoat, Lynn Hall, and Adrienne Minecci.

II. New Custodians

A. Blasine Penkowski

JJHCS declines to add Blasine Penkowski, JJHCS's Chief Strategic Customer Officer, as an additional custodian. SaveOnSP first raised Ms. Penkowski in the June 23, 2023 Joint Letter in support of its motion to expand the scope of discovery to companies besides JJHCS. As JJHCS explained at that time, JJHCS has "no reason to believe that Ms. Penkowski would have unique documents or communications relating to the SaveOnSP or JJHCS's response to the SaveOnSP program." (Dkt. No. 122 at 12.)

Nothing in SaveOnSP's August 28 letter alters that conclusion. First, Ms. Penkowski's involvement with JALT is not relevant to this lawsuit and does not justify adding her as a custodian. As we have repeatedly explained, responsibility for the CarePath program resides principally with Katie Mazuk, Vice President, Patient Engagement and Customer Solutions and her reporting line. Ms. Mazuk is a member of JALT and an existing JJHCS custodian. As a result, any JALT communications that reference CarePath copay assistance, SaveOnSP, or this litigation already are captured by Ms. Mazuk's documents. (Dkt. No. 122 at 9.) This is reflected in the documents cited by SaveOnSP: Ms. Mazuk is included on JJHCS_00101570, JJHCS_00001668, JJHCS_00001830, and JJHCS_00101641.

Second, SaveOnSP's citation to a handful of non-JALT documents does not alter this conclusion. [redacted]

Third, SaveOnSP's citation to documents alleging that Ms. Penkowski has "unique information" about SaveOnSP or TrialCard similarly fall flat. Ms. Penkowski's receipt of a publicly available March 2022 report is not a reason to add her as a custodian. *See* JJHCS_00074697. Nor are Statements of Work between JJHCS and TrialCard. *See* JJHCS_00025908; JJHCS_00025517; JJHCS_00025532; JJHCS_00024511; JJHCS_00025594. SaveOnSP argues that because Ms. Penkowski signed these Statements of Work that she somehow has "unique information" about JJHCS's relationship with TrialCard. But that logic isn't borne out by the documents—nor is the nature of JJHCS's relationship with TrialCard central to the litigation.

Finally, none of the documents referenced in SaveOnSP's August 28 letter justifies discovery from apex personnel, i.e., high-level executives, like Ms. Penkowski. *See, e.g.*, *Lauris v. Novartis AG*, 2016 WL 7178602, at *4 (E.D. Cal. Dec. 8, 2016) (requiring "more than mere speculation to order [the producing party] to include the apex custodians in [a] search protocol"). "Mere speculation" that Ms. Penkowski's position as "a senior executive might increase the relevance of [her] files" is not a basis for designating her as a custodian. *Mortg. Resol. Servicing, LLC v. JPMorgan Chase Bank, N.A.*, 2017 WL 2305398, at *3 (S.D.N.Y. May 18, 2017).

SaveOnSP offers no reason to believe that Ms. Penkowski would have unique documents or communications specific to SaveOnSP or JJHCS's response to the SaveOnSP program.

B. Scott White

JJHCS declines to add Scott White as an additional custodian. As JJHCS has previously represented to the Court and to SaveOnSP, Scott White is Company Group Chairman, North America Pharmaceuticals, a high-ranking executive with no day-to-day responsibilities for CarePath. He is therefore entitled to protection from undue burden and harassment under the apex doctrine. *See Lauris*, 2016 WL 7178602, at *4; *Mortg. Resol. Servicing, LLC*, 2017 WL 2305398, at *3. SaveOnSP again relies on JJHCS_00001704 to state that because Mr. White received a copy of the SaveOnSP presentation video, he is relevant to this litigation. And again, following that logic, any person who received, sent, saw, or heard the SaveOnSP video would be a potential custodian.

Moreover, any relevant documents in Mr. White's possession related to JALT would be found in documents belonging to Ms. Mazuk, a member of JALT and an existing custodian. This, too, is reflected in the documents cited by SaveOnSP. *See, e.g.*, JJHCS_00001704, JJHCS_00011154, JJHCS_00041213, JJHCS_00001830, and JJHCS_00001668, which all include Ms. Mazuk on the email chain.

SaveOnSP's claim that Mr. White is likely to have unique documents is unpersuasive. SaveOnSP relies on JJHCS_00100210 [redacted]

Finally, SaveOnSP's citation to various Statements of Work and change orders do not alter this view. *See* JHCS_00039767, JJHCS_00039772, JJHCS_00039696, JJHCS_00039374, JJHCS_00039378, JJHCS_00039382, JJHCS_00039625, and JJHCS_00039879. None indicate that Mr. White has "unique information" about JJHCS's relationship with TrialCard—nor is JJHCS's relationship with TrialCard central to the litigation, and in any event, TrialCard is already producing documents pursuant to a subpoena served by SaveOnSP.

C. Karen Lade

JJHCS declines to add Karen Lade as an additional custodian. SaveOnSP first proposed Ms. Lade in the June 23, 2023 Joint Letter. Ms. Lade works as a Product Director, Rheumatology Marketing. Based on its investigations to date, JJHCS has no reason to believe that Ms. Lade would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. To the extent Ms. Lade's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other agreed-upon

custodians, including Heith Jeffcoat, Silviya McCool, Lauren Pennington, and Spilios Asimakopoulos. [redacted]

D. L.D. Platt

JJHCS declines to add L.D. Platt as an additional custodian. Based on its investigations to date, JJHCS has no reason to believe that Mr. Platt would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. As JJHCS explained in its July 28, 2023 Supplemental Responses and Objections to SaveOnSP's First Set of Interrogatories, Mr. Platt was [redacted] To the extent Mr. Platt has documents relating to this Action, those would be protected by the attorney-client privilege, work product doctrine, or another applicable privilege or protection from disclosure. *See* JJHCS_00027974, JJHCS_00027996, and JJHCS_00027998. In addition, in the documents cited by SaveOnSP Mr. Platt is neither the sender, nor the sole receiver of these emails, and more importantly, is not a participant in the discussion.

E. Ernie Knewitz

JJHCS declines to add Ernie Knewitz as an additional custodian. Based on its investigations to date, JJHCS has no reason to believe that Mr. Knewitz would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. As JJHCS explained in its July 28, 2023 Supplemental Responses and Objections to SaveOnSP's First Set of Interrogatories, Mr. Knewitz was "[redacted] JJHCS's July 28, 2023 Supplemental Responses & Objections to SaveOnSP's First Set of Interrogatories. To the extent Mr. Knewitz has documents relating to this Action, those would be protected by the attorney-client privilege, work product doctrine, or another applicable privilege or protection from disclosure.

In addition, Mr. Knewitz's involvement with JALT does not merit his addition as a custodian. As JJHCS has made clear, responsibility for the CarePath program resides principally with Katie Mazuk, Vice President, Patient Engagement and Customer Solutions and her reporting line. Ms. Mazuk is a member of JALT and an existing JJHCS custodian. Any JALT communications that reference CarePath co-pay assistance, SaveOnSP, or this litigation, already are captured by Ms. Mazuk's documents. (*See* Dkt. No. 122 at 9.) This is reflected in the documents cited by SaveOnSP. *See* JJHCS_00001859, JJHCS_00041213.

Finally, SaveOnSP again relies on JJHCS_00001704 to state that because Mr. Knewitz received a copy of the SaveOnSP presentation video, he is relevant to this litigation. That is a nonstarter for the reasons discussed above.

F. John Hoffman

JJHCS declines to add John Hoffman as an additional custodian. Based on its investigation to date, JJHCS has no reason to believe that Mr. Hoffman would have unique documents or communications relating to SaveOnSP or JJHCS's response to the SaveOnSP program. SaveOnSP's reliance on JJHCS_00027236, JJHCS_00026852, JJHCS_00101570, and JJHCS_00114446 are not to the contrary. Mr. Hoffman is neither the sender, nor the sole receiver of these emails, and more importantly, is not involved in the discussion. To the extent Mr. Hoffman's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other agreed-upon custodians, including John King and Silas Martin.

G. Silas Martin

JJHCS ran specific search terms over Silas Martin's documents to satisfy its discovery obligations as to RFP No. 20. *See* Sept. 6, 2023 Ltr. from E. Shane to E. Snow at 2. The production of Mr. Martin's non-privileged documents responsive to RFP No. 20 were part of JJHCS's Eighth Production of Documents on September 1, 2023, and will be substantially completed before the September 24, 2023 substantial completion deadline.

Very truly yours,

/s/ Julia Long
Julia Long

EXHIBITS 8-12

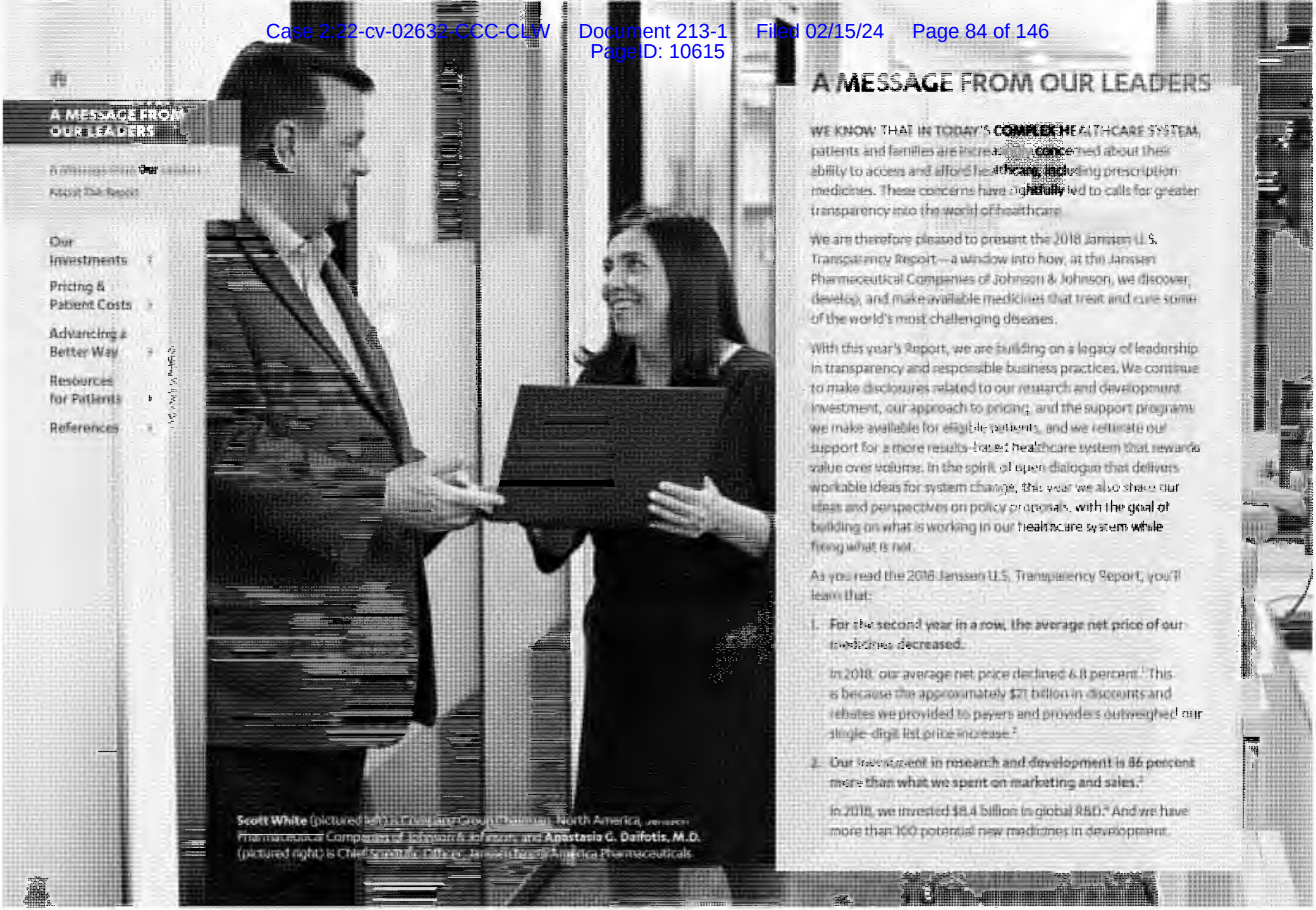
CONFIDENTIAL – FILED UNDER SEAL

Exhibit 13

janssen | Pharmaceutical Companies of Johnson & Johnson

2018

JANSSEN U.S. TRANSPARENCY REPORT



Scott White (pictured left) is Chief Strategy Group Chairman, North America, Janssen Pharmaceutical Companies of Johnson & Johnson and **Anastasia G. Daifotis, M.D.** (pictured right) is Chief Scientific Officer, Janssen Research & Development

A MESSAGE FROM OUR LEADERS

WE KNOW THAT IN TODAY'S COMPLEX HEALTHCARE SYSTEM, patients and families are increasingly concerned about their ability to access and afford healthcare, including prescription medicines. These concerns have rightfully led to calls for greater transparency into the world of healthcare.

We are therefore pleased to present the 2018 Janssen U.S. Transparency Report—a window into how, at the Janssen Pharmaceutical Companies of Johnson & Johnson, we discover, develop, and make available medicines that treat and cure some of the world's most challenging diseases.

With this year's Report, we are building on a legacy of leadership in transparency and responsible business practices. We continue to make disclosures related to our research and development investment, our approach to pricing, and the support programs we make available for eligible patients, and we reiterate our support for a more results-based healthcare system that rewards value over volume. In the spirit of open dialogue that delivers workable ideas for system change, this year we also share our ideas and perspectives on policy proposals, with the goal of building on what is working in our healthcare system while fixing what is not.

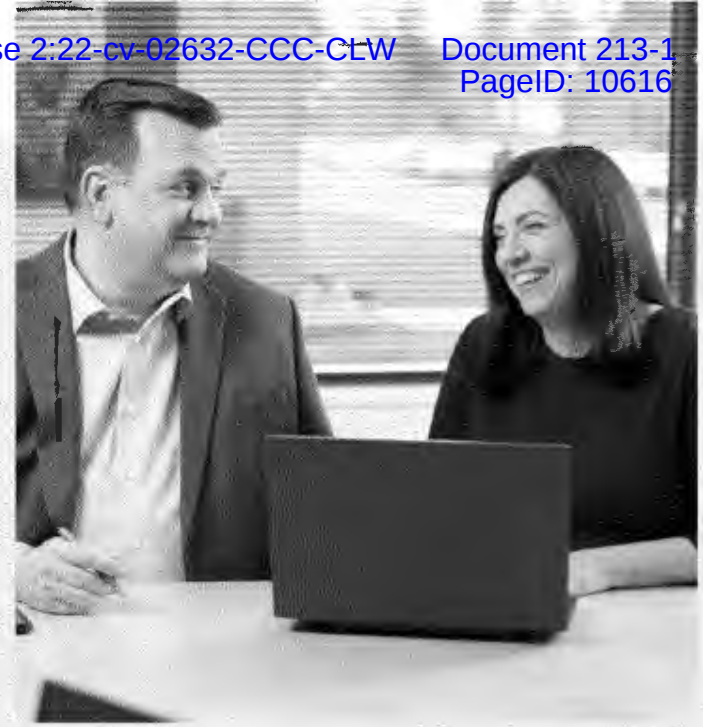
As you read the 2018 Janssen U.S. Transparency Report, you'll learn that:

1. **For the second year in a row, the average net price of our medicines decreased.**

   In 2018, our average net price declined 6.8 percent.[1] This is because the approximately $71 billion in discounts and rebates we provided to payers and providers outweighed our single-digit list price increase.[2]

2. **Our investment in research and development is 86 percent more than what we spent on marketing and sales.[3]**

   In 2018, we invested $8.4 billion in global R&D.[4] And we have more than 100 potential new medicines in development.



3. **We've developed a common-sense way to make clearer for patients what they may pay for our medicines.**

   Starting with our most frequently prescribed medicine, XARELTO®, we're voluntarily including list price and typical out-of-pocket costs in our U.S. pharmaceutical TV advertising, with additional information available online at janssen.com/drcdisclosures.

4. **We helped approximately 1 million patients with access, affordability, and treatment support through the Janssen CarePath program.[5]**

   This includes approximately 550,000 commercially insured patients who reduced their out-of-pocket costs through the Janssen CarePath Savings Program.[6]

5. **We worked with stakeholders to advance our ideas for a better healthcare system.**

   We've forged value-based contracts with payers, participated in partnerships to explore value-based care models, and proposed practical policy solutions to bring down costs for patients.

We make these disclosures at a critical moment in the history of U.S. healthcare. In recent years, increased transparency has yielded important insights about why patients feel they're paying more out-of-pocket for their medicines. Government leaders are translating those insights into action, taking steps intended to lower costs. The current moment offers an unprecedented opportunity to minimize the barriers that stand between patients and affordable access to their medicines.

Historic medical advances add to the urgency of the task. It is now possible to treat diseases once thought beyond a cure, and new scientific insights promise advances yet to come. In decisions we as a society make about the future of healthcare, we need to remember the full value such advances ultimately deliver. For example, over the last two decades patient outcomes for diseases including HIV, heart disease, and lung cancer have improved substantially, while the cost of treating those diseases has decreased or risen only modestly. The fact that this progress is due largely to medicines[7] is yet another reminder that all patients should have access to the medicines they need.

The status quo is not acceptable, and we are committed to generating sustainable solutions. We want these solutions to give hope to patients today—and foster the life-changing innovation that will give ever-increasing hope to patients tomorrow.

In the meantime, greater transparency is a critical step toward giving patients the clarity they need about their healthcare options and out-of-pocket costs (and patients need greater transparency from every stakeholder in the system). We want this Report to be useful to them—and to anyone who shares our commitment to developing a more results-based healthcare system that delivers what we all want: greater access to care, at more manageable cost, and, most importantly, better health for all.

Sincerely,

Scott White
Company Group Chairman
North America Pharmaceuticals
Johnson & Johnson

Anastasia G. Daifotis, M.D.
Chief Scientific Officer
Janssen North America
Pharmaceuticals

ABOUT THIS REPORT

The 2018 Janssen U.S. Transparency Report is our third annual report providing greater transparency into our business operations. The report provides an inside look at how we at the Janssen Pharmaceutical Companies of Johnson & Johnson put our values into practice across our U.S. business, from how we choose to invest our resources in the development of new treatments, to how we value and price our medicines, to how we work to support access to our medicines.

The information provided in this report pertains to Janssen's U.S. operations, except where indicated otherwise. In June 2017, Johnson & Johnson completed the acquisition of Actelion Ltd, a leader in pulmonary arterial hypertension. Actelion information is incorporated into the 2018 Janssen U.S. Transparency Report, which reflects Actelion's first full year as part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

All financial data in this report reflects our fiscal year, which covers the period between January 1, 2018 and December 30, 2018. Other disclosures in this report cover the period between January 1, 2018 and December 31, 2018; any exceptions are noted. Analyses conducted for the purposes of this report may be different from the methodologies used by other companies. The data have not been audited and the report is not intended to address all our corporate disclosures.

Throughout this report we refer to additional resources where readers can find more information about specific Janssen and Johnson & Johnson programs and disclosures. Financial performance information of our parent company, Johnson & Johnson, and its subsidiaries, as well as its "Cautionary Note Regarding Forward-Looking Statements," can be found in Johnson & Johnson Annual Reports, available at jnj.com/about-jnj/annual-reports. Information on Johnson & Johnson environmental, social, and governance measures can be found in the Johnson & Johnson Health for Humanity Report, available at healthforhumanityreport.jnj.com.

This report and a one-page executive summary are also available to read and download at janssen.com/us/transparency-report.

BY THE NUMBERS: JANSSEN IN 2018

$8.4 billion
invested globally in research and development[8]

86% more
invested in R&D than we spent on marketing and sales[9]

100+
medicine candidates in development as a result of our investments in R&D

6
new medicines approved by the FDA over the past 5 years[10,11]

~140
active collaborations in 2018 with academia, pharmaceutical and biotech peers, and public/private sector partners

24
clinical data transparency requests to the Yale Open Data Access (YODA) project, all approved[12]

~$21 billion
total discounts and rebates[13]

6.3%
average list price change[14]

~6.8%
average net price change[15]

4
value principles that help us define the value of our medicines

550,000
commercially insured patients helped with out-of-pocket costs through the Janssen CarePath Savings Program[16]

OUR INVESTMENTS

AT JANSSEN, WE ARE COMMITTED TO delivering transformational medical innovation that can change the trajectory of health for humanity. We focus our research and development (R&D) on preventing and treating diseases in areas of medicine where we can make the most meaningful impact. In 2018, Janssen invested $8.4 billion in R&D globally,[1] making us one of the top R&D investors in any industry, anywhere in the world.[2] This investment in R&D far exceeds what we spent to market our medicines.[3]

In this chapter, we describe our investments in R&D and our efforts to improve the R&D process by collaborating with patients and other partners throughout the healthcare system.

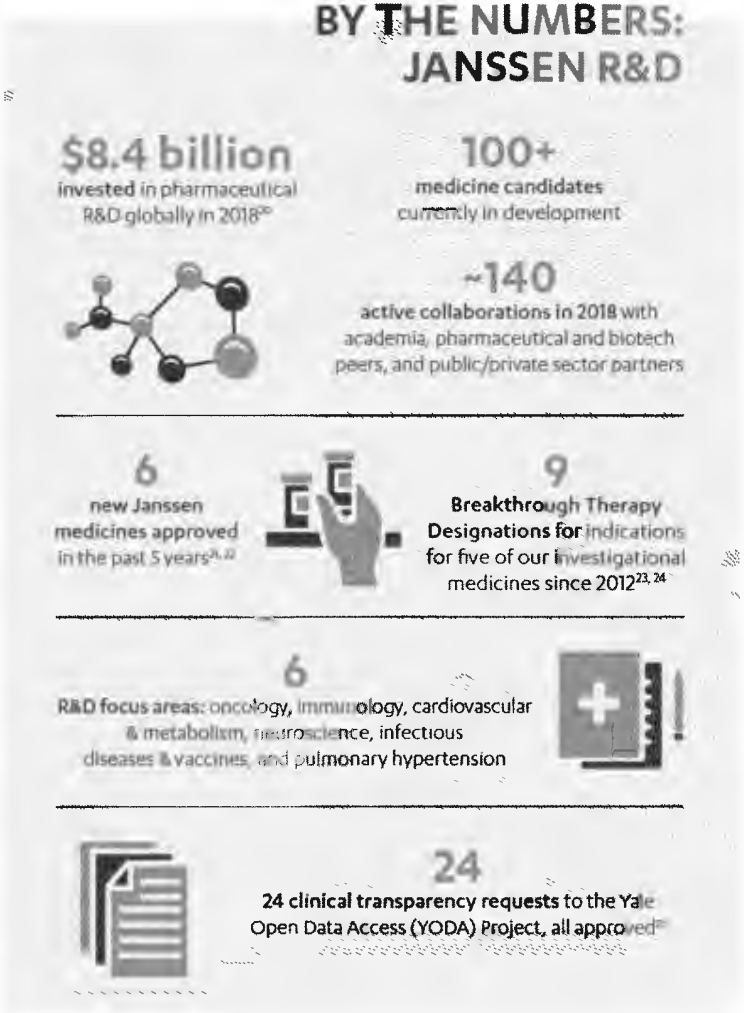
Research & Development at Janssen: Our Approach

At Janssen, we create transformational medicines to improve the health of humanity. To do so, we harness and scale breakthroughs in science and technology. We invest in modern data science to increase both the effectiveness and efficiency of R&D. We also invest significantly in new drug modalities such as engineered cells, engineered viruses, and gene therapy to make a profound difference for patients, a difference not achievable using today's traditional approach of small molecules and monoclonal antibodies. We move science and technology forward, publishing extensively so that all may benefit. Our R&D is currently focused on the following areas of medicine:

- Cardiovascular & Metabolism
- Immunology
- Infectious Diseases & Vaccines
- Neuroscience
- Oncology
- Pulmonary Hypertension

Disease Area Strongholds and Pathway Area Strongholds

Within our six areas of medicines, we have developed Disease Area Strongholds (DASs) to dive deeper into specific areas of medical research that draw on our historical strengths. We combine our discovery, clinical development, and patient and health system insights to streamline the process of bringing a medicine from the laboratory to patients. Our aim within each DAS is to treat the disease as early in its course as possible and to create regimens (including medicine combinations) that head progressively toward a cure. For example, in oncology we have DASs that advance the development of transformative medicines for hematologic malignancies (blood cancers) and for prostate cancer. In neuroscience, we have established DASs for neurodegeneration and for mood disorders, while our



DASs in cardiovascular & metabolism are exploring retinal diseases as well as thrombosis. These are just a few of the diseases that Janssen teams focus on in this highly effective model for drug development.

As part of a new approach in R&D, we have created Pathway Area Strongholds (PASs), where we are pursuing research in validated biological pathways that we believe are central to several diseases that can cut across therapeutic areas. For example, in immuno-oncology we potentiate, or enhance, the body's own immune system to fight cancer.

MEET OUR R&D COLLEAGUES

WAYNE DREVETS, M.D.

Scientific Vice President and Disease Area Stronghold Leader for Mood Disorders, Neuroscience

THERE'S A GAP BETWEEN WHAT WE'RE LEARNING about the brain and the way we practice psychiatry, which is more or less the same as it was when I was in training. That's one of the main reasons I made the decision to move over to the pharmaceutical industry. I wanted to help develop new treatments that would make a difference for patients.

Dr. Drevets oversees the development of new medicines for mood disorders, including major depressive disorder, treatment-resistant depression and suicidality. He and his team are focused on developing new treatments for patients for whom existing treatments have inadequately helped and, ultimately, on finding cures for these complex diseases. In March 2019, Janssen received approval from the FDA for a new medicine for adult patients with treatment-resistant depression, marking the first new mechanism of action for major depressive disorder in decades, reflecting years of work on the part of the mood disorder team at Janssen and other researchers.[76]

Trained as a psychiatrist and a scientist, Dr. Drevets began his career at leading universities and the National Institute of Mental Health where he used noninvasive neuroimaging technologies to study what happens in the brains of people being treated for mental illnesses. He was energized by the scientific advances he helped bring about, but he also wanted to deliver those advances to patients in the form of new treatments.

"There's a gap between what we're learning about the brain and the way we practice psychiatry, which is more or less the same as it was when I was in training," he said in a recent interview. "That's one of the main reasons I made the decision to move over to the pharmaceutical industry. I wanted to help develop new treatments that would make a difference for patients."

Today, Dr. Drevets and his team are exploring ways to develop new medicines that are guided by specific biological markers—also known as biomarkers—of various mental illnesses. They are also figuring out how to develop medicines that will work faster than current treatments, most of which take three weeks or more to have an effect.

Learn more about how Dr. Drevets is leading the way toward a future where no one has to suffer the debilitating effects of complex mental illnesses by visiting innovation.org.

CHIARA MAGNONE, PH.D

Vice President, Metabolic Complications, Janssen Research & Development and Director of the Janssen Cardiovascular & Metabolism Discovery Facility in Boston

WE'RE HOPING TO USE PRECISION MEDICINE TO revolutionize metabolic medicine the same way it's revolutionized oncology. Patients with type 2 diabetes and its related complications often receive a one-size-fits-all treatment, even though not everyone responds in the exact same way. Our mission is to change that.

Dr. Magnone comes to work every day thinking about ways to bring the latest scientific advances to the treatment of type 2 diabetes. Despite the rapidly growing prevalence of the disease—hundreds of millions of people around the world live with it—few new treatments have been developed in recent years and most of the existing medicines help manage symptoms rather than address the underlying disease. Meanwhile, many patients suffer debilitating complications, like blindness, stroke, and kidney disease, and the cost of treatment has soared.

Dr. Magnone hasn't always worked in the cardiovascular and metabolism field—her early research focused on the brain, studying multiple sclerosis—but she has always been drawn to areas where the medical need is great.

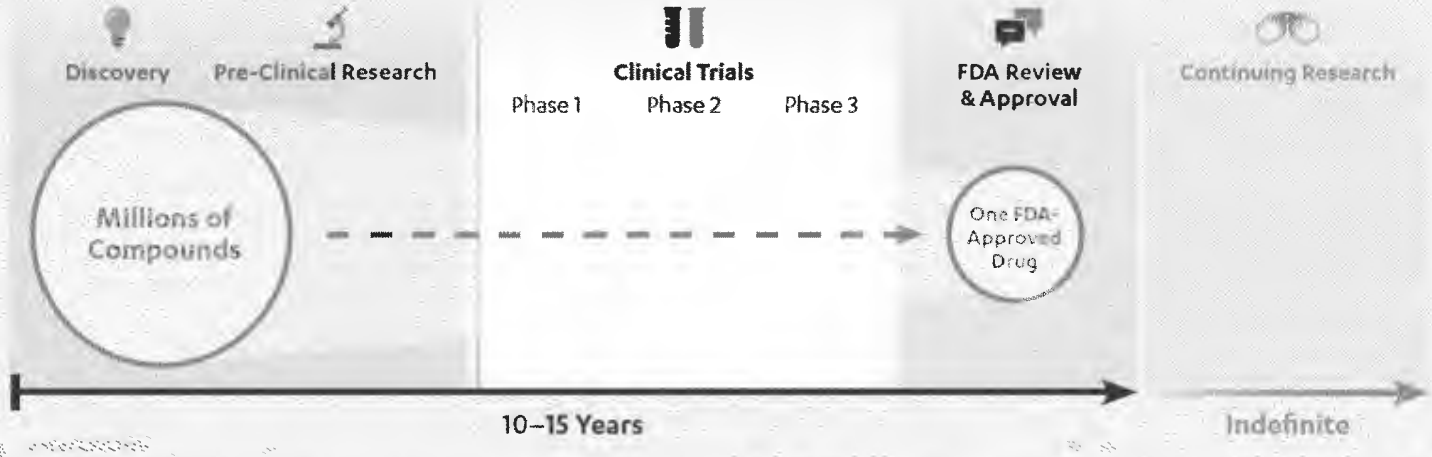
Dr. Magnone and her team of leading experts are optimistic about the new pathways they are exploring together. They are researching how to bring some of the most innovative approaches in cancer treatment—such as precision medicine and once-in-a-lifetime therapies—to patients with type 2 diabetes.

"We're hoping to use precision medicine to revolutionize metabolic medicine the same way it's revolutionized oncology," she recently told a colleague. "Patients with type 2 diabetes and its related complications often receive a one-size-fits-all treatment, even though not everyone responds in the exact same way. Our mission is to change that."

Dr. Magnone believes patients with type 2 diabetes deserve treatments that prevent or slow the progression of their disease-related complications, and that is what she hopes to deliver. Read more about Dr. Magnone's mission at jnj.com.

ENABLING INNOVATION AT JANSSEN

Bringing a new medicine to patients entails several stages of research, conducted over many years, and comes with significant cost and financial risk. Developing a medicine and then gaining approval from the U.S. Food and Drug Administration (FDA) typically takes 10–15 years[27] and costs between $157 million and $2 billion.[28,29]



Discovery & Pre-Clinical Research: We start by working to understand the molecular and cellular pathways together with the genetic and environmental influences that drive disease. Based on this understanding, we then select a target or pathway before identifying agents and beginning the many cycles of design, optimization, and investigation to determine their predicted efficacy and safety in humans before advancing to clinical trials. Many potential medicines do not proceed past this point.

Clinical Trials: Clinical trials for the development of new medicines are typically conducted in phases. In Phase I, we study the investigational compound in a small group of volunteers to learn more about the safety of the medicine and how it interacts in the body. In Phase II, we evaluate the medicine's effectiveness and side effects as a function of the dose (amount) given, often in several hundred patients who have the disease the medicine is intended to treat. In Phase III, the medicine is given to larger groups of people with an aim to confirm its effectiveness at a chosen dose, evaluate how it works in different populations, and compare it to the standard of care or commonly used treatments for that disease. All clinical trials are designed in partnership with regulatory agencies such as the FDA. For some medicines, these development phases may be blended to get medicines to patients faster. A potential new medicine may fail at any stage of clinical trial development.

FDA Review & Approval: If research shows that a medicine makes a real difference for patients, and its benefits outweigh its risks, we seek approval from the FDA. The FDA conducts a thorough analysis of the medicine. If approved, the medicine can then be made available to patients.

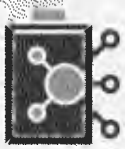
Continuing Research: After we receive FDA approval to bring a medicine to patients, significant additional research may be conducted to understand how the medicine works in a real-world setting; explore expanded indications, dosages, or product formulations; monitor safety; and better understand the value our medicine has for patients, providers, and the health system at large. Investments in this stage of research may lead to medicine improvements or identification of new groups of patients that may benefit from the medicine.

RESEARCH CONTINUES AFTER FDA APPROVAL

While most conversations about R&D focus on the period before FDA approval, research does not stop when a medicine is approved. We continue to study our medicines after we receive FDA approval to bring a medicine to patients. We may conduct clinical trials to determine whether the medicine may be used to treat additional diseases, assess how it compares with additional existing or emerging therapies, or gain additional insights on safety or efficacy by collecting and analyzing data from the use of the medicine in everyday practice of medicine. Specifically, we conduct studies to:

1. Understand how the product works in a real-world setting.

We may generate clinical information on the use, risks, and benefits of a medicine derived from data on how a medicine is being used in the real world, outside of a clinical trial. For example, we studied the clinical and economic impact of starting anti-retroviral therapy (ART) soon after an HIV diagnosis among Medicaid patients, and we found that the sooner ART was started the better their health outcomes and the lower their healthcare costs.[30]



2. Explore expanded indications, dosages, or product formulation.

We may conduct clinical trials to determine whether the use of our medicines may be expanded, for example to treat additional diseases. For one of our medicines for patients with atrial fibrillation and deep vein thrombosis, we received approval for an expanded indication to reduce the risk of serious cardiovascular (CV) events, including stroke, myocardial infarction (MI) and CV death, for patients with chronic coronary or peripheral artery disease (CAD/PAD). This new indication is based on results from the landmark COMPASS trial, which showed a significant 24 percent reduction of the risk of major CV events in patients with chronic CAD and/or PAD, when taken in combination with low-dose aspirin.[31]

3. Gather more information on safety, efficacy, use, strength, purity, or potency.

When a medicine is approved, we often commit or are required to perform post-marketing research to gather additional information about the product's safety, efficacy, use, strength, purity, or potency. These studies supplement routine activities to assess safety, for example through adverse event reporting and other post-marketing research efforts. This work can help resolve uncertainties that remain at the time of approval, like assessments of the long-term use of a medicine, or the effect on infants when used during pregnancy or while breastfeeding. To put this research in context, one of our treatments for immunology disorders, including psoriasis, psoriatic arthritis, and Crohn's disease, was first approved in 2009. Since then, we have completed 16 post-marketing required studies and commitments and are on track to complete the remaining nine in a timeframe agreed upon with the FDA.

4. Better understand the value our medicine has for patients, providers, and the health system at large.

We study the potential of our medicines to reduce costs to health systems and society. For example, we found that patients taking one of our medicines used to treat schizophrenia (a long-acting injectable) were significantly less likely to have an encounter with the criminal justice system in the 12-month period after starting the medicine than in the 12-month period before.[32] The results suggest that these medicines could potentially reduce cost associated with the criminal justice system, including cost related to incarceration.[33]

Collaborating with Experts and Entrepreneurs Outside Janssen

We recognize that the best science does not always reside in a single company. It exists within us and all around us. Bringing new medicines to patients requires collaboration and partnership. A large part of our success stems from the work we do with dynamic, diverse partners, including startup companies, academic centers, hospitals and health systems, government agencies, biotechnology organizations, and other biopharmaceutical companies.

These collaborations allow us to use our resources more efficiently and further enable the process of developing breakthrough medicines to create real value for patients, their families, and communities. Today, we have approximately 140 active collaborations and partnerships from discovery to late stage development. Here are some examples:

- **Through our commitment to partner with those whose innovative thinking will bring new and creative solutions to the field of medicine,** Janssen is collaborating with Legend Biotech USA, Inc. to develop a chimeric antigen receptor T cell therapy (CAR-T), which harnesses the body's own immune system to fight cancer. CAR-T therapy is a type of immunotherapy, which involves extracting a patient's white blood cells, genetically modifying them in a laboratory, and re-administering the modified cells to the patient to permit the cells to attack the disease. The hope is that treatment will lead to longer remissions from disease for patients where conventional treatments are no longer providing benefit. Every year in the U.S., more than 30,000 patients are diagnosed with multiple myeloma, and more than 12,000 patients die from the disease.[34]
- **Janssen is collaborating with Arrowhead Pharmaceuticals, Inc. to develop an early stage ribonucleic acid interference (RNAi) candidate,** along with utilization of a platform that blocks production of disease-causing proteins. This brings us closer to developing an effective therapy with the potential to increase rates of functional cure for people living with chronic hepatitis B viral infection. Hepatitis B is a life-threatening viral infection of the liver, which if it becomes chronic, can cause cirrhosis—scarring of liver tissue—and liver cancer. The World Health Organization cites hepatitis B as a global public health problem with 257 million people living with the disease and 887,000 deaths in 2015.[35] While a preventative vaccine is available, cure rates for those infected remain low and most patients require lifelong therapy. RNAi therapy candidates have been shown to have an effect on hepatitis B viral infection replication pathways and on the production of viral proteins.[36] Our work with this investigational treatment and other assets within our clinical development pipeline makes us optimistic that we can achieve higher rates of functional cure for patients worldwide.

JOHNSON & JOHNSON INNOVATION—JLABS

Getting a life sciences company up and running is a challenge. We are passionate about helping healthcare startups succeed. Our mission is to remove hurdles and empower life science innovators through access to infrastructure, community, and specialized expertise. JLABS, the Johnson & Johnson network of open innovation health sciences incubators, provides life science startup companies access to the tools they need to take their ideas from concept to commercialization. JLABS now has a total of 12 facilities, nine located in the U.S., each with varied access to state-of-the-art equipment, prototype labs, and a year-round innovator curriculum focused on commercial and business development. JLABS is a "no-strings-attached" model, which means entrepreneurs are free to develop their science while holding on to their intellectual property.

Over six years,
JLABS has grown to support 450+ companies. In 2018 alone, there was a 44 percent increase in the total number of companies we supported.

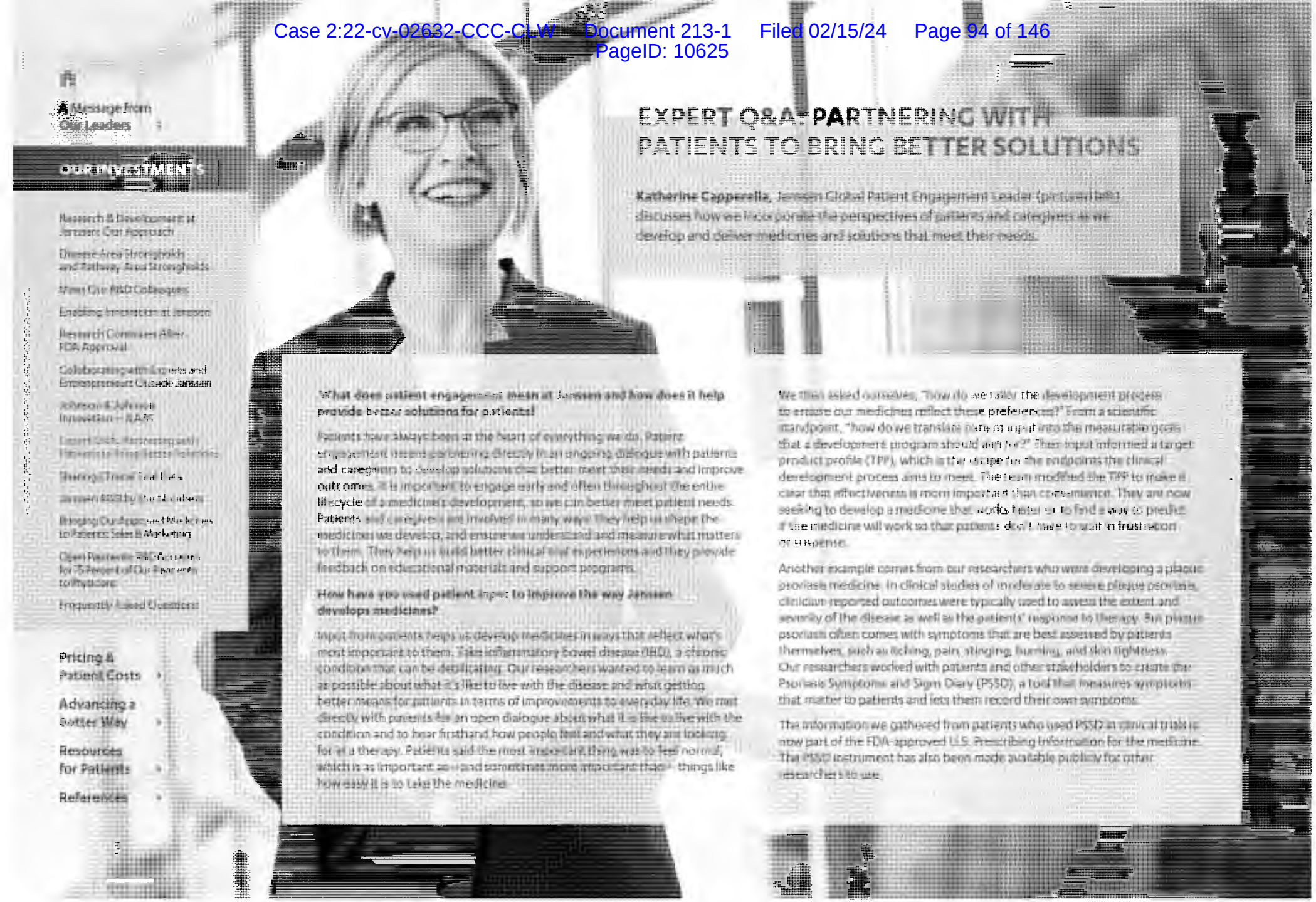
100+ companies
participated in JLABS "Inside Scoop" pitch day events, at which more than 1,100 attendees gained access to venture capitalists, angel investors, and other funding sources.

Approximately $6 million
in grant funding and residency costs were awarded in more than 30 Quickfire Challenges focused on key issues like health tech wearables and lung cancer treatments.[37]

170 JPALs,
which include industry experts and business leaders from the Johnson & Johnson Family of Companies, coached and mentored JLABS companies throughout the year.

Startups now have access
to JPODs, networking hubs that connect life sciences innovators to Johnson & Johnson. These first-of-their-kind connection points are meant to accelerate the development of early-stage healthcare solutions that address significant unmet needs in medical devices, pharmaceuticals, consumer, and health technologies.

To learn more about JLABS, visit jlabsinnovation.com.



EXPERT Q&A: PARTNERING WITH PATIENTS TO BRING BETTER SOLUTIONS

Katherine Capparella, Janssen Global Patient Engagement Leader (pictured left), discusses how we incorporate the perspectives of patients and caregivers as we develop and deliver medicines and solutions that meet their needs.

What does patient engagement mean at Janssen and how does it help provide better solutions for patients?

Patients have always been at the heart of everything we do. Patient engagement means partnering directly in an ongoing dialogue with patients and caregivers to develop solutions that better meet their needs and improve outcomes. It is important to engage early and often throughout the entire lifecycle of a medicine's development, so we can better meet patient needs. Patients and caregivers are involved in many ways. They help us shape the medicines we develop, and ensure we understand and measure what matters to them. They help us build better clinical trial experiences and they provide feedback on educational materials and support programs.

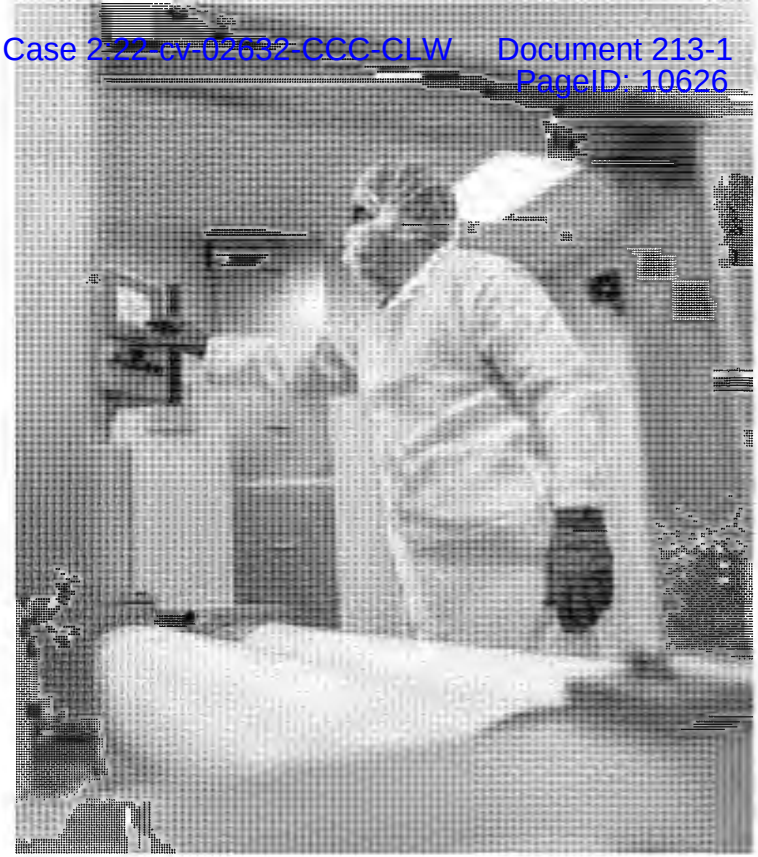
How have you used patient input to improve the way Janssen develops medicines?

Input from patients helps us develop medicines in ways that reflect what's most important to them. Take inflammatory bowel disease (IBD), a chronic condition that can be debilitating. Our researchers wanted to learn as much as possible about what it's like to live with the disease and what getting better means for patients in terms of improvements to everyday life. We met directly with patients for an open dialogue about what it is like to live with the condition and to hear firsthand how people feel and what they are looking for in a therapy. Patients said the most important thing was to feel normal, which is as important as—and sometimes more important than—things like how easily it is to take the medicine.

We then asked ourselves, "How do we tailor the development process to ensure our medicines reflect these preferences?" From a scientific standpoint, "how do we translate patient input into the measurable goals that a development program should aim for?" That input informed a target product profile (TPP), which is the recipe for the endpoints the clinical development process aims to meet. The team modified the TPP to make it clear that effectiveness is more important than convenience. They are now seeking to develop a medicine that works faster or to find a way to predict if the medicine will work so that patients don't have to wait in frustration or at expense.

Another example comes from our researchers who were developing a plaque psoriasis medicine. In clinical studies of moderate to severe plaque psoriasis, clinician-reported outcomes were typically used to assess the extent and severity of the disease as well as the patients' response to therapy. But plaque psoriasis often comes with symptoms that are best assessed by patients themselves, such as itching, pain, stinging, burning, and skin tightness. Our researchers worked with patients and other stakeholders to create the Psoriasis Symptoms and Signs Diary (PSSD), a tool that measures symptoms that matter to patients and lets them record their own symptoms.

The information we gathered from patients who used PSSD in clinical trials is now part of the FDA-approved U.S. Prescribing Information for the medicine. The PSSD instrument has also been made available publicly for other researchers to use.



Sharing Clinical Trial Data

Making clinical trial results available allows other researchers to learn from our efforts. This advances science and benefits public health in important ways.

Like others in our industry, we disclose information about our clinical trials on clinicaltrials.gov, the largest U.S. public registry, and we seek to publish the results of company-sponsored trials and health economic studies in peer-reviewed medical journals. But we don't stop there.

In a first-of-its-kind agreement with the Yale University School of Medicine, we share pharmaceutical, device, and consumer product clinical trial data through the Yale Open Data Access (YODA) Project. Its mission is to advocate for the responsible sharing of clinical research data, open science, and research transparency.

Launched in 2014, the YODA Project serves as an independent review panel, evaluating researchers' requests for access to participant-level trial data and research reports, which provide extensive details about the methods and results of a clinical trial. Researchers can use these clinical trial data in their own scientific or medical research to increase medical knowledge and improve public health.

The YODA Project informs and enhances future initiatives to promote clinical trial data-sharing.[38] For example, a recent study allowed outside researchers to look at gender differences in weight gain in patients with inflammatory bowel disease treated with one of our medications. Another study conducted by the World Health Organization compared different therapies used to treat multidrug-resistant tuberculosis, including one we produce, to inform global treatment guidelines. Data sharing and data transparency, helped significantly by the YODA Project, are quickly becoming the new standard in pharmaceutical and medical device science and in clinical research more broadly.

In 2018, the YODA Project received 24 requests for data from researchers and physicians at institutions and academic centers in the U.S. and around the world, all of which were approved by the YODA Project.[39] Additionally, 11 papers were published this past year as a result of data we shared.[40] For more information about the YODA Project and to request access to data from Janssen's clinical trials, please visit yoda.yale.edu.

BY THE NUMBERS: 2018 YODA RESULTS[41]

24	100%	11
requests for data	requests approved	papers were published using YODA data

Our leadership in clinical trial data transparency has been recognized by external organizations like Bioethics International. In 2017, Johnson & Johnson achieved the highest overall clinical trial transparency score—100 percent—from Bioethics International in its Good Pharma Scorecard (GPS), an annual index that ranks the top 20 biopharmaceutical companies and new FDA-approved drugs on key ethics, human rights, and public health criteria.[42] The GPS report evaluated clinical trial registration, results reporting, clinical study report synopsis sharing, and journal article publication rates for new drugs approved by the FDA in 2014 that were sponsored by large drug companies.[43]

Janssen R&D by the Numbers

We are at a pivotal moment in the history of medicine. It is now possible to prevent, manage, and even cure diseases that were once severely debilitating or even fatal. And more advances lie ahead.

That's why we have continued our industry-leading investment in discovering and developing transformational medicines for patients facing some of the world's most challenging diseases.

In 2018, Janssen increased to $8.4 billion our investment globally in R&D; this amount represents a significant portion of Johnson & Johnson's overall 2018 R&D investment of $10.8 billion.[44] Our R&D expenditures enable us to discover, test, and develop new medicines as well as to demonstrate the efficacy, safety, and regulatory compliance of our medicines prior to approval. R&D resources are also used to improve existing, FDA-approved products.

This investment has enabled us to advance more than 100 medicine candidates. Over the past five years (2014-2018), we have had a total of six new medicines approved by FDA.[45,46] Five of these six new medicines were granted priority review by FDA. Priority review is an expedited review program reserved for products that treat a serious condition and would provide a significant improvement for patients in terms of safety or effectiveness.[47] During this same time period, we received eight FDA Fast Track designations, which facilitate development and expedite review of drugs that treat serious conditions and fill unmet medical needs. We also received approvals for more than 30 expanded indications or new product formulations that enable new groups of patients to benefit from our medicines.[48]

Since the FDA established the Breakthrough Therapy Designation in 2012, we have received nine FDA Breakthrough Therapy Designations for indications for five of our investigational medicines.[49,50] A Breakthrough Therapy Designation is a process that expedites the development and review of an investigational medicine that is intended to address a serious condition when preliminary clinical evidence indicates that the medicine may demonstrate a substantial improvement over other available treatments.[51]

Our global investment in R&D significantly exceeds our investment in global marketing and sales activities. In 2018, we invested $8.4 billion in our global R&D[52] and we spent $4.5 billion on global marketing and sales activities, which means we spent 86 percent more on R&D than we did on marketing and sales.[53] We make this comparison using global figures because our investment in R&D cannot be segmented by region. The R&D activities we undertake around the world collectively contribute to medicine development, regardless of location.

The marketing and sales figures in this report are even more specific than what is described in Johnson & Johnson financial statements. Johnson & Johnson financial statements do not separate marketing and sales expenses from other expenses associated with running the company. They combine marketing and sales expenses with other items in a line item described as "Selling, Marketing and Administrative Expenses" (SM&A). This SM&A figure accounts for much more than pharmaceutical marketing and sales expenses. It includes administrative and overhead activities that are not related to marketing or sales, such as expenses for insurance, legal, finance, and product distribution. It also pertains to all of the businesses in the Johnson & Johnson Family of Companies, which, in addition to pharmaceuticals, include medical devices and consumer products; finally, it is a global, not U.S., figure.

FAST FACT

In 2018, we invested

86% more in R&D

than we spent on marketing and sales.[54]

Bringing Our Approved Medicines to Patients: Sales & Marketing

After we have FDA approval for an innovative medicine, we invest in providing accurate, up-to-date information about the medicine to healthcare professionals and patients. In 2018, we spent $2.5 billion in the U.S. for pharmaceutical marketing and sales activities,[55] including communications with healthcare professionals about the medicines' approved uses, effectiveness, side effects, benefits, and risks. The expenditures also include patient education and direct-to-consumer communication.

The patients and healthcare professionals who rely on our medicines place their trust in the reliability of our clinical research, the rigor of our scientific publications, the independence of the medical education we fund, and the integrity of our professional relationships.

Healthcare providers with real-world clinical experience in specific therapeutic areas are uniquely qualified to provide education and insights into new advancements regarding our products. Known as "peer-to-peer" education, this type of interaction can address potential treatment gaps as it allows providers to objectively discuss important medical information with expert colleagues regarding the appropriate use of our products. We work with healthcare providers for peer-to-peer education with the goal of improving the health of patients and driving improved clinical outcomes through transparent, compliant activities.

Our marketing and sales activities adhere to a high level of legal requirements and ethical standards.

We follow all laws and regulations regarding the promotion of prescription medicines and submit promotional materials to the FDA. Our marketing and sales activities adhere to industry ethics standards and codes of conduct, including the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals and the PhRMA Guiding Principles on Direct-to-Consumer (DTC) Advertisements about Prescription Medicines. We view these guidelines as a starting point and challenge ourselves to deliver even more for patients. For more information about how we are implementing the recently enhanced PhRMA principles regarding DTC advertisements, see the chapter titled "Pricing & Patient Costs."

When we market our medicines, we ensure that the information we share with patients and healthcare professionals is accurate and current. Our review process, which is governed by an internal team of medical, compliance, and legal experts, evaluates all information about our medicines that we share with physicians or patients to ensure it is accurate and credible. ■

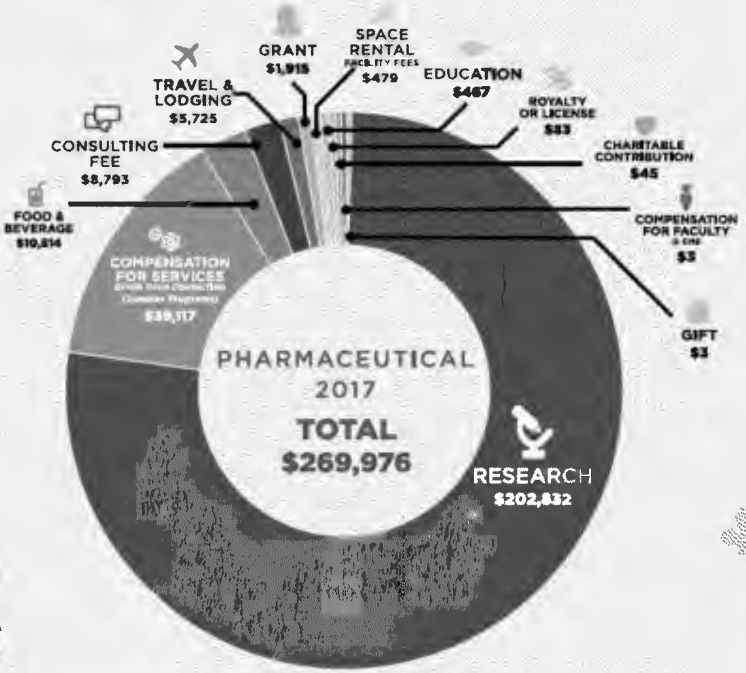
OPEN PAYMENTS: R&D ACCOUNTS FOR 75 PERCENT OF OUR PAYMENTS TO PHYSICIANS

In accordance with the Physician Payment Sunshine Act, we disclose to the U.S. Centers for Medicaid and Medicare Services (CMS) the compensation or transfers of value that we provide as a part of our sales and marketing outreach to educate healthcare professionals about our medicines. These transfers of value include, but are not limited to, meals, travel expenses, medical textbooks, and scientific articles. We make this information available on jnj.com. The information is also available to the public through the CMS Open Payments database.

These "Sunshine Act" disclosures also include payments we make to physicians for their guidance during the R&D process, including assistance with the design and conduct of clinical trials. In fact, these research-related payments account for approximately 75 percent of our 2017 payments to physicians and teaching hospitals.[56]

We anticipate that 2018 Open Payments data will be available through CMS on June 30, 2019.

Numbers contained in the chart below are shown in $1,000s.



RESEARCH	Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives
COMPENSATION FOR SERVICES (OTHER THAN CONSULTING)	Compensation for services other than consulting, including serving as faculty or a speaker at a venue other than a continuing education program • Fees for speaking at program on our company's behalf • Aquisition payments
FOOD & BEVERAGE	Meals, whether paid directly or reimbursed, may be provided in conjunction with • Consulting services • Training • Educational and other business discussions with physicians
CONSULTING FEE	Product development • Training • Development of educational materials and disease management programs • Unblinded market research
TRAVEL & LODGING	Travel, whether paid directly or reimbursed, in conjunction with • Consulting services • Product training
[illegible]	Sponsorship of an educational event, patient advocacy event, or publication • Sponsorship of fellowships for fellow and resident training • Certified independent educational activities (i.e., activities certified by a continuing medical education provider) • Non-certified medical education activities
[illegible]	Space Rental or Facility Fees (Teaching Hospital Only) • Booth or exhibit space rental • Facility rental for product training or clinical studies

EDUCATION	Medical textbooks • Scientific journal articles
ROYALTY OR LICENSE	Payment of royalty or license fees for inventions or significant contributions towards the development of a new innovation, often based on product sales over a pre-determined period of time
CHARITABLE CONTRIBUTION	Monetary donation (only represents charitable contributions required to be disclosed under Open Payments); for more on J&J charitable contributions, visit: jnj.com/our-giving
COMPENSATION FOR FACULTY OF CME	Indirect payment by a third party organization to speakers at an accredited educational program, funded by an educational grant from a J&J company
GIFT	Open Payments categories are specified by regulation and do not provide for an "other" category; the gifts category may be used when there is no appropriate category available

FREQUENTLY ASKED QUESTIONS (FAQ)

What role does the National Institutes of Health (NIH) play in developing medicines, and do pharmaceutical companies benefit from government-funded research?

The National Institutes of Health (NIH) and other U.S. government agencies play an important role in medical research, primarily funding and conducting basic research, namely the exploration of the cellular and molecular changes involved in the development of disease.[42] This important work furthers our understanding of disease and can help identify potential targets for medicine development. The knowledge generated by public investments in basic science is critical for laying the foundation for future pharmaceutical innovation.[43]

Research by government institutions like the NIH sometimes leads directly to the discovery of a molecule or technology platform that has the potential to become a novel medicine or vaccine, although this happens infrequently.[44] Basic research is rarely specific enough to yield an investigational molecule that could be turned into a medicine.

While the NIH funds research to understand the problem, we fund research on solutions—treatments for the problem. The vast majority of the long, financially risky, and costly process to discover and develop new medicines that meet the stringent safety and efficacy requirements of the FDA is conducted and funded by the biopharmaceutical industry. In 2017 alone, industry investments were approximately $97 billion, triple NIH's $32.4 billion spending on research in the same year.[45] In fact, the amount of research U.S. biopharmaceutical companies undertake to bring new medicines to patients makes us one of the most research-intensive sectors in the country, and the source of the majority of industry spending on R&D worldwide.[46]

There is no straight line from government-funded basic research to a marketable medicine or medical device. A study of NIH grants awarded over a 27-year period (1980-2007) showed that only 8.4% of NIH grants were directly acknowledged in a patent for a medicine, device, or other technology, and less than 1% were directly acknowledged in a patent associated with a marketed medicine.[47]

Further, sometimes public institutions hold intellectual property rights to research that a pharmaceutical company carries forward. In cases where a collaboration leads to intellectual property held by a partner, pharmaceutical companies pay royalties, and when the risks of drug discovery are shared, partners receive milestone payments and/or royalties paid on revenues of marketed medicines.

Continued on next page

FREQUENTLY ASKED QUESTIONS (FAQ)

What is the difference between Janssen's expenditures on R&D and sales and marketing highlighted in this report and expenditures for Sales, Marketing and Administration that Johnson & Johnson reports in financial filings?

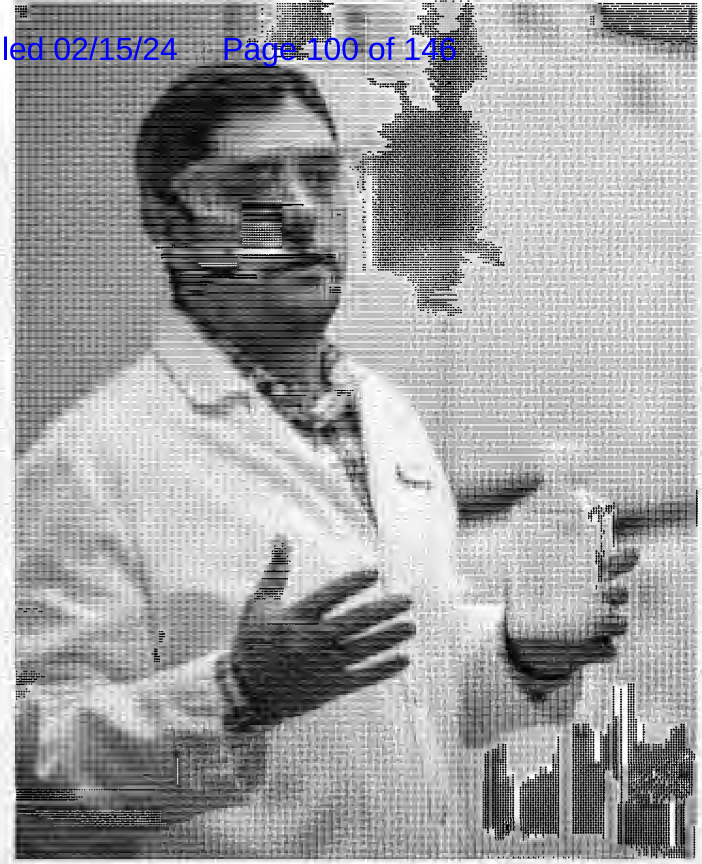
Johnson & Johnson is a healthcare company comprised of three business segments: pharmaceuticals (Janssen), medical devices and consumer products. In its financial statements, Johnson & Johnson reports a total figure for Sales, Marketing & Administration (SM&A) which combines marketing, sales, and administrative expenses such as insurance, legal, finance and product distribution across all three business segments.

The figures we disclose in this report are for Janssen-specific sales and marketing and do not include administrative expenses. In order to help address questions about Janssen Investments in R&D and Janssen sales and marketing expenditures, we detail this information on pages 14 and 15 of this report. Specifically, Janssen spent $8.4 billion on R&D globally and $4.5 billion on marketing and sales globally in 2018. This means Janssen invested 86% more in R&D than sales and marketing.

Does Janssen work with generic manufacturers to provide access to medicine samples for testing?

We support intellectual property protections that encourage medical innovation as well as policies that enable generic medicines to be broadly available at a low cost. We cooperate with generic manufacturers so they have access to samples of our medicines at reasonable, market-based prices.

For certain medicines, FDA has required a Risk Evaluation and Mitigation Strategy (REMS) that restricts distribution of the medicine so that its safe use can be more closely managed. In those cases, before providing testing samples to generic manufacturers, we request that they seek an FDA determination that they have protocols in place to protect patient safety that are comparable to our REMS programs. We rely on FDA's determination that safety protections are comparable when working with generic manufacturers. We then establish supply agreements with the manufacturer and provide samples. We have entered into supply agreements and provided samples to all companies whose safety protocols are determined to be sufficient, and we plan to continue to do so in the future.



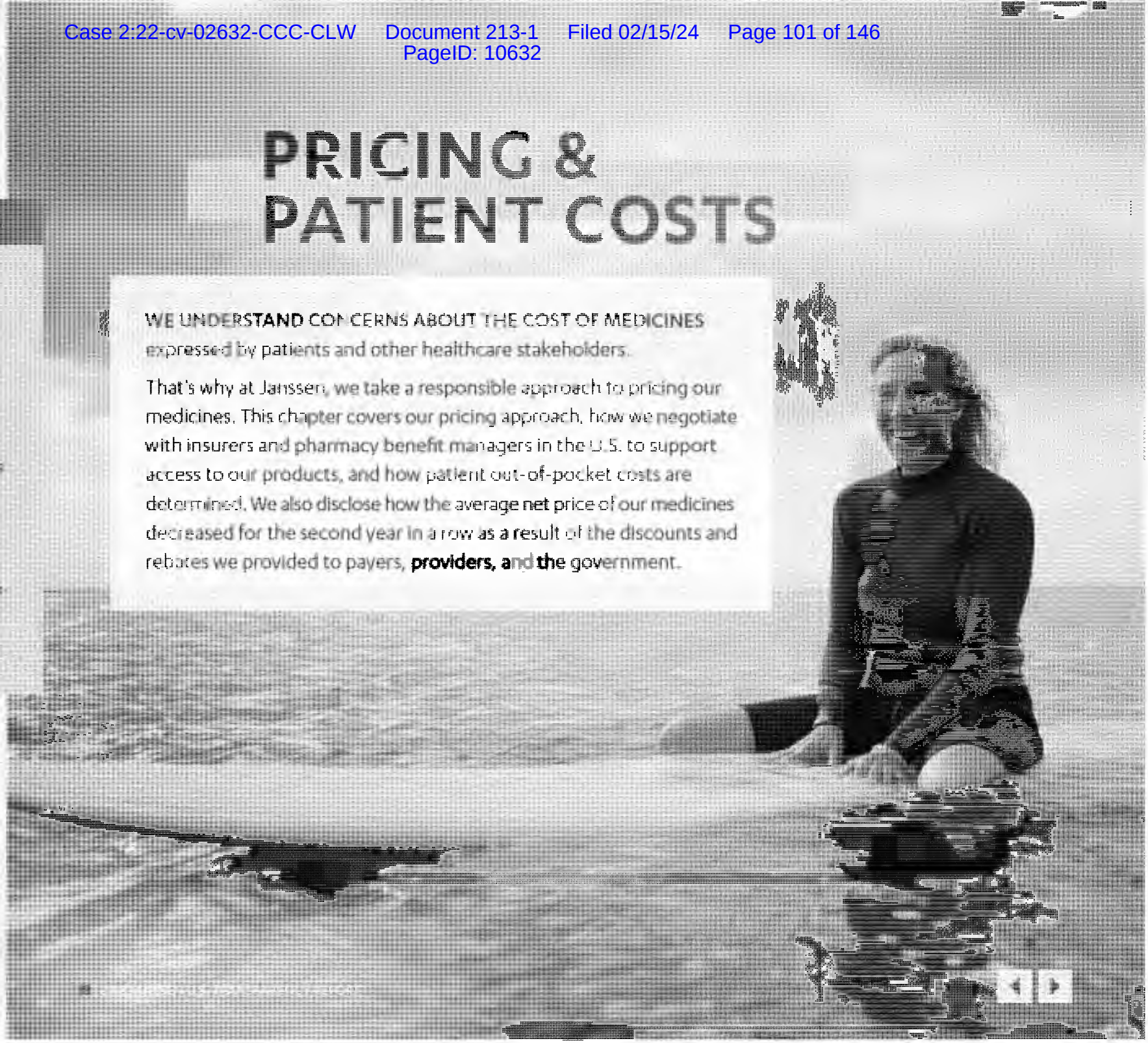
Are acquisitions of pharmaceutical companies included in your R&D spending that you disclose?

No. When we acquire a pharmaceutical company, related acquisition expenses are considered a business transaction and are not included in our total R&D investment. R&D expenditures relate to the processes of discovering, testing and developing new products, upfront and milestone payments made to partners in connection with R&D collaborations, improving existing products, and ensuring product efficacy and regulatory compliance prior to launch. We invest in these activities to fulfill our commitment to delivering transformational medical innovation.

PRICING & PATIENT COSTS

WE UNDERSTAND CONCERNS ABOUT THE COST OF MEDICINES expressed by patients and other healthcare stakeholders.

That's why at Janssen, we take a responsible approach to pricing our medicines. This chapter covers our pricing approach, how we negotiate with insurers and pharmacy benefit managers in the U.S. to support access to our products, and how patient out-of-pocket costs are determined. We also disclose how the average net price of our medicines decreased for the second year in a row as a result of the discounts and rebates we provided to payers, **providers, and the** government.



Our Pricing Approach

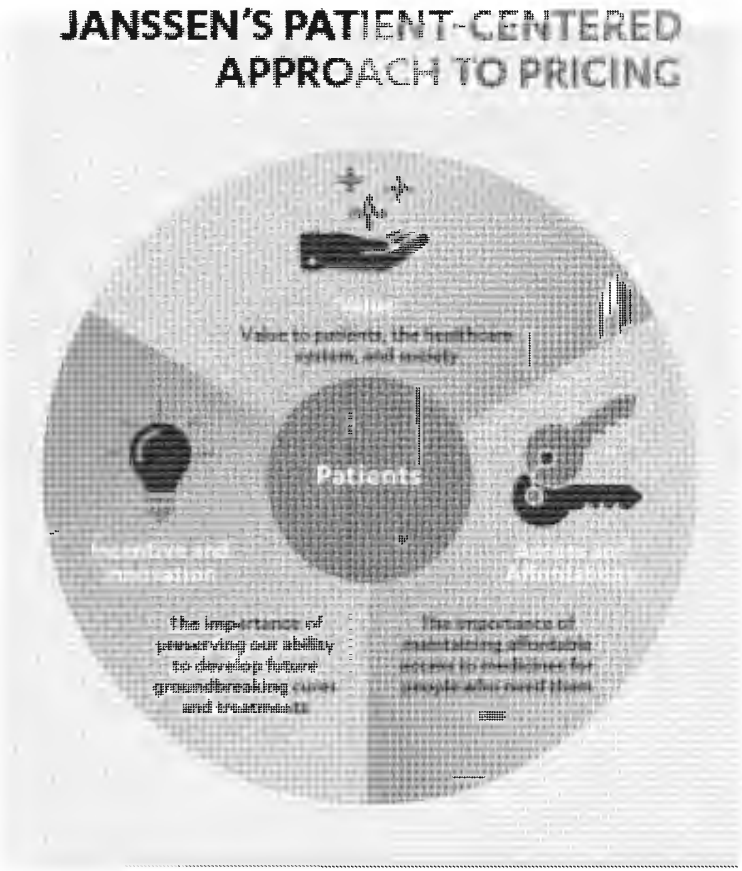
At Janssen, we take a responsible approach to pricing that recognizes our dual responsibility to patients today and patients tomorrow. Patients today need access to our medicines. Patients tomorrow count on us to deliver cures and treatments for the most challenging, intractable diseases. When we set the list price for our medicines, we balance:

- **Value to patients, the healthcare system, and society.** We consider how the medicine will improve patient health. We also assess the medicine's potential to reduce other costs—surgeries, hospital stays, or long-term care, for example—and the improvement the medicine represents over the existing standard of care. (For more about our Value Assessment Principles, see the "Advancing a Better Way" chapter.)
- **The importance of ensuring affordable access to medicines for people who need them.** We work with insurers, pharmacy benefit managers, governments, hospitals, physicians, and other providers of care so that patients who are prescribed our medicines can get access to them.
- **The importance of preserving our ability to develop future groundbreaking cures and treatments.** We have an obligation to ensure that the sale of our medicines provides us with the necessary resources to invest in R&D to address serious, unmet medical needs.

We go through a lengthy process to gather the information necessary to assess the medicine according to these factors. We use this information to determine the value of our medicine compared to what is, or will be, available to treat the same condition—be it other medicines, surgery, or other forms of healthcare. We also seek input on our pricing approach from external experts who provide feedback to help us make sure the price we set is appropriate.

List Price vs. Net Price

Based on these considerations, we determine an initial list price for our medicine. The list price is a starting point that is ultimately reduced by the substantial discounts, rebates, and fees we provide to insurance companies, pharmacy benefit managers (PBMs), government programs, and others. We pay required discounts to U.S. government programs, and we negotiate with private payers so that they will cover our medicines and make them available to patients at a lower out-of-pocket cost. (See more in the "Expert Q&A: List Price vs. Net Price" section.)



DISCOUNTS AND REBATES FROM PHARMACEUTICAL COMPANIES

The discounts and rebates we provide insurers, PBMs, governments, hospitals, physicians, and other care providers support broad access to our medicines. We also pay fees to pharmaceutical wholesalers to distribute our medicines. Here is more information about how these discounts, rebates, and fees work:

Hospitals and Clinics
Pharmaceutical manufacturers provide discounts on medicines to hospitals and clinics for inclusion on their formularies. Under a federal program known as the 340B Drug Discount Program, we are also required to provide significant discounts on certain medicines purchased by specific categories of hospitals, clinics, and health centers that meet federal eligibility requirements.

Payers
Public and private payers as well as PBMs have a role in managing prescription drug purchases for patients.

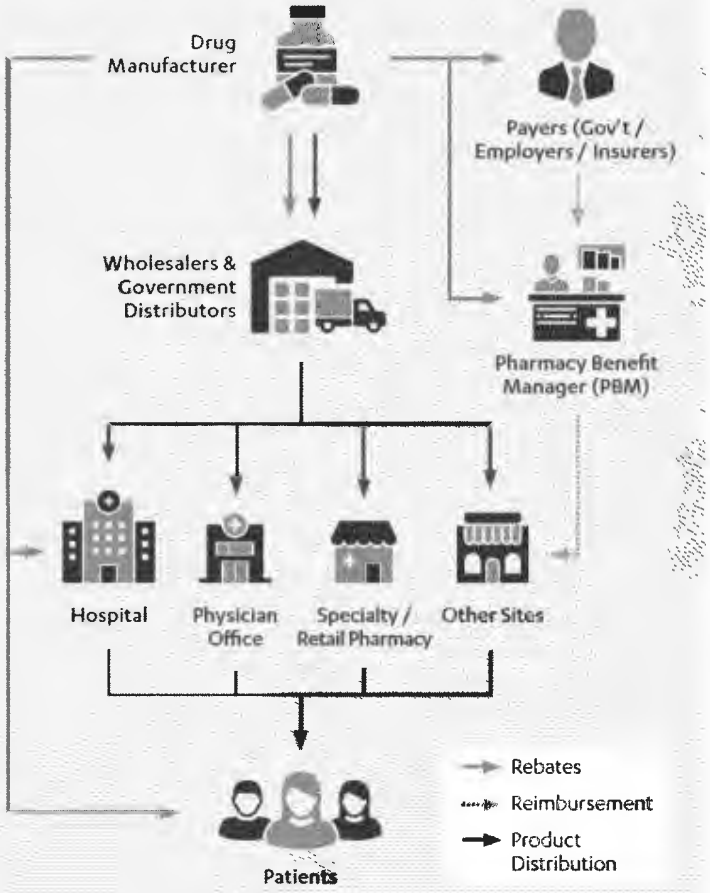
For patients with private insurance coverage, negotiations for medicine formulary placement result in rebates from the pharmaceutical company to commercial health plans and PBMs. (For more information, see the "Expert Q&A: List vs. Net Price" section.)

In order to participate in public programs, we are required to give specific mandatory discounts to government insurers such as state Medicaid departments and the U.S. Department of Veterans Affairs. In addition, we provide discounts and rebates through negotiations with the private health insurance companies and PBMs who administer benefits for Medicaid and Medicare. (For more information, see the "Discounts and Rebates in Federal Health Programs" section in the 2017 U.S. Transparency Report.)

Wholesalers and Distributors
Pharmaceutical companies pay fees to wholesalers and distributors—companies that buy our medicines in bulk and distribute them to pharmacies and other healthcare providers.

AN EXAMPLE OF THE PHARMACEUTICAL SUPPLY CHAIN

From pharmacies to hospitals to insurance companies to distributors, many entities are involved in getting a medicine from the pharmaceutical company to the patient. Together, they make up the pharmaceutical supply chain. This chart depicts a typical route a medicine takes from drug manufacturer to patient, including the roles of multiple players that make up the process.



EXPERT Q&A: LIST PRICE VS. NET PRICE

Blasine Penkowski, Chief Strategic Customer Officer (pictured left), shares more about the difference between list and net price and how discounts, rebates and fees work.

Can you provide more detail about how list price becomes net price?

The list prices we set are reduced by a combination of discounts and rebates. Some of these are mandated by the government. Others we negotiate with commercial payers.

To government insurers, such as state Medicaid departments and the U.S. Department of Veterans Affairs, we are required to give substantial discounts. The government requires that pharmaceutical companies provide specific mandatory discounts on medicines in order to participate in these programs; manufacturers are also required to provide discounts to certain hospitals.

In addition, we provide discounts and rebates through negotiations with the private health insurance companies and pharmacy benefit managers (PBMs) who administer benefits for Medicaid and Medicare.

We also work with the commercial health insurance companies and PBMs that manage the purchase of medicines for those with private insurance coverage. They determine what medicines will be included on their formulary (the list of products they cover) and the out-of-pocket amounts patients will pay for those medicines. Formulary determinations are based, in part, on payers' negotiations with pharmaceutical companies. These negotiations result in rebates from the pharmaceutical company to the payer.

We also pay fees to pharmaceutical wholesalers and distributors—companies that buy medicines in bulk and distribute them to pharmacies and other healthcare providers.

Why does Janssen negotiate with private payers?

Commercial payers like PBMs and health insurers have lists of prescription medicines they will cover and help pay for called drug formularies, which are updated regularly. Within the formularies, medicines are placed on "tiers" that correspond with patients' out-of-pocket costs. For example, a medicine on tier one will have a lower out-of-pocket cost than a medicine on tier three. Because multiple treatments exist for many conditions, payers create competition among pharmaceutical companies who want their medicine to be placed on a tier with a lower copay. Products on tiers with lower copays are called "preferred" products.

In contract negotiations, we give payers information they can use to evaluate the overall value of our medicines. We offer discounts and rebates on our medicines with the objective of gaining payer coverage and favorable formulary placement so that our medicines are accessible and affordable to patients.

We are competitive in our negotiations so that payers enable patients to have access to our medicines. However, what patients pay may not reflect the discounts and rebates we provide to payers.

How do net prices affect what patients ultimately pay for their medicines?

It's important to keep in mind that payers decide where medicines belong on their formularies and the type of health insurance benefits patients have. These decisions determine what patients pay for medicines, often referred to as out-of-pocket costs.

Recent IQVIA research found that many patients' cost-sharing is based on list—not net—price, particularly when patients pay for prescriptions in their deductible period—in the beginning of the year—or when their medicines are subject to coinsurance—in other words, when they pay a percent of the medicine cost rather than a flat copay. Out-of-pocket costs in the deductible period or for coinsurance account for half of all patient out-of-pocket spending on branded medicines.[65] Recently, some payers have announced that they will start applying a portion of manufacturer rebates to the price patients pay.[66,67] While this benefits only a small percentage of commercially insured patients,[68] it is an important first step.

Further, despite the tremendous value medicines deliver, in the U.S., patients typically pay a greater share of the cost for medicines than they do for other forms of healthcare. On average, patients pay 13 percent of prescription drug costs compared to three percent of hospital care costs[69]—even though the medicine could help keep the patient out of the hospital.

Our Net Prices Declined 6.8% in 2018

At Janssen, we limited our annual aggregate list price increase to single-digit percentages in 2018, as we have in past years.[70] We provided approximately $21 billion in discounts and rebates on our medicines—or a discount rate of 47 percent.[71] Taking into account these discounts and rebates, the aggregate net impact of price on our business was -6.8 percent, a greater decrease than our -4.6 percent average net price change in 2017.[72] In the chart below, you will see list and net price changes of our medicine portfolio for the past five years. Our business remained strong because of increased use of our medicines, demonstrating the value of our innovations to patients and healthcare providers.

Our net price decline comes as prescription medicine costs are leveling out overall and spending on other healthcare services is rising. The average net prices for branded medicines in the U.S. grew an estimated 1.5 percent[73] in 2018 while the total rate of medical inflation in the U.S. rose approximately 2 percent.[74] Total prescription drug spending grew only 0.4 percent in 2017[75] while overall healthcare expenditures increased 3.9 percent.[76] As stakeholders seek ways to curb healthcare spending in the U.S., it is important to remember the role prescription drugs play in overall costs.

JANSSEN U.S. PRICING OVERVIEW[77]

[77] Pricing overview reflects U.S. product portfolio including pharmaceutical products marketed by the company. Products are primarily in the areas of Immunology, Oncology, Cardiovascular & Metabolism, Infectious Diseases, Neuroscience, and Pulmonary Arterial Hypertension.

[78] Annual percent change vs. prior year calculated at product level and weighted across company's U.S. product portfolio.

[79] Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC).

[80] Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.

OUR COMMITMENT TO PROVIDING MEANINGFUL INFORMATION ON PRESCRIPTION DRUG COSTS

At Janssen, we believe in empowering patients with the information they need to make informed decisions about their healthcare. As part of our commitment to addressing patients' need for clear, meaningful, and relevant information about the cost of their prescription medications, we are including the list price and typical patient out-of-pocket costs in our U.S. pharmaceutical TV advertising for our medicines, starting with our most frequently prescribed medicine, XARELTO®

A wide range of variables contribute to what patients actually pay for a medicine. Insurance coverage, dosing, site of care, and access to support programs can all cause this amount to vary from the list price.

We developed a way to accurately depict what most patients pay on a monthly basis for specific medicines in our portfolio. The amount reflects the out-of-pocket costs of approximately 75% of U.S. patients according to approved pharmacy claims, after insurance has been applied. Most people who see our ads will likely pay in this more specific range.

This action builds upon the enhancements the Pharmaceutical Research and Manufacturers of America (PhRMA) made to its Guiding Principles on Direct-to-Consumer (DTC) Advertisements about Prescription Medicines. Our commitment to the PhRMA voluntary principles will give patients pricing information that is appropriately contextualized.

WE SURVEYED 2,230 PEOPLE, AND HERE'S WHAT WE HEARD:

We listened to American consumers and patients across a wide range of diseases areas, including Atrial Fibrillation, Psorasis, Crohn's, Prostate Cancer, and Leukemia.

1,446 patients

784 general population

We shared different ways pricing information could be included in U.S. pharmaceutical TV ads.

Only list price

Typical out-of-pocket costs and list price

Directing patients to a website

79% of patients and consumers prefer to know the amount they will have to pay for a pharmaceutical medication (Out-of-Pocket Costs).

12% of patients and consumers prefer to know the List Price of a pharmaceutical medication.

Patients and consumers also found it helpful to have more detailed cost information on a medicine's website, including:

Cost to them

Insurance factors

Ways to save

Patient Out-Of-Pocket Costs

While the estimated net prices for branded medicines across the industry have increased below the rate of medical inflation in three of the past four years,[81, 82, 83, 84] these pricing trends are not reflected in many patients' experiences at the hospital, doctor's office, or pharmacy counter. The average out-of-pocket burden has risen dramatically. In fact, out-of-pocket costs for branded medicines increased 48 percent from 2013 to 2016.[85]

One reason patients' out-of-pocket spending has grown is a change in how health insurance is designed and pharmaceutical benefits are managed. Over the last decade, high-deductible health plans—plans that require large, upfront deductibles and higher rates of cost-sharing in exchange for lower premiums—have become more common. Enrollment in high-deductible health plans has expanded from 4 percent in 2006 to 29 percent in 2018.[86] The use of coinsurance, where insurers in some plans charge patients a percentage of the medicine's list price instead of a fixed dollar copayment, has also increased.[87]

BY THE NUMBERS: OUR PRICING IN CONTEXT

6.3%
average list price change[88]

-6.8%
average net price change[89]

~$21 billion
total discounts and rebates[90]

However, the average out-of-pocket burden has risen dramatically. In fact, from 2013 to 2016, out-of-pocket costs for branded medicines increased 48%.[91]

These changes in benefit design make affordability significantly more challenging for some patients. High deductibles expose patients to larger upfront out-of-pocket expenses for medicines and other services. And coinsurance often leaves them responsible for larger payments, especially for specialty or highly innovative medicines, than traditional flat-rate copays.[92] Indeed, among patients covered by large employers, much of the increase in total out-of-pocket spending for healthcare can be attributed to increasing cost-sharing. The average payment toward deductibles and coinsurance rose 176 percent and 67 percent, respectively, between 2006 to 2016.[93] For medicines specifically, deductibles and coinsurance represent a significantly larger share of out-of-pocket spending than they did more than a decade ago, growing from 7 percent in 2004 to 49 percent in 2016.[94]

FAST FACT

For medicines specifically, deductibles and coinsurance represent a significantly larger share of out-of-pocket spending than they did more than a decade ago, growing from 7 percent in 2004 to 49 percent in 2016.[95]

Benefit Design and the Patient Experience

Benefit design can dramatically affect patient access to, and the affordability of, medicines. The hypothetical examples on the following page feature patients taking the same specialty medicine for a chronic condition under different types of insurance plans. The medicine has a negotiated monthly net price of $300 ($3,600 annual) and a monthly list price of $500 ($6,000 annual). For additional examples, please visit phrma.org.

Research shows that when patients pay a greater share for their medicines, patient health can suffer, and there can be negative consequences.[96] Patients with higher out-of-pocket costs are more likely to abandon their new prescriptions at the pharmacy: 69 percent of commercial patients did not start therapy when faced with out-of-pocket costs exceeding $250.[97] Similarly, high out-of-pocket costs can contribute significantly to medication or treatment "non-adherence" in patients with chronic or serious illnesses, such as rheumatoid arthritis[98] or breast cancer.[99]

When patients do not fill and adhere to their medicines, the result can be higher costs for other healthcare services.[100] Such decisions may reduce payer and health system pharmacy costs in the short term, but over the long term, lack of adherence results in poorer health outcomes and can lead to higher overall system costs.[101] According to one study, the U.S. could save $213 billion annually if medicines were used appropriately.[102] The Congressional Budget Office has estimated that for every 1 percent increase in the number of prescriptions filled by Medicare beneficiaries, spending on medical services decreases by about 0.2 percent.[103]

EXAMPLES OF THE IMPACT OF BENEFIT DESIGN ON PATIENT OUT-OF-POCKET COSTS

Example 1: Emily

Emily has health insurance through her employer. In an effort to distribute her healthcare costs evenly over the year, Emily selected a Preferred Provider Organization (PPO) plan that features smaller copay costs and no deductible in exchange for a higher premium.

When Emily goes to the pharmacy to fill her prescription, she learns that because her medicine is in a specialty tier, it is subject to her insurer's coinsurance rate of 20 percent instead of a flat copayment rate. If her coinsurance were based on the insurer's negotiated net price, her monthly cost would be $60. However, because her insurer bases coinsurance rates on list price, Emily's monthly out-of-pocket payment at the pharmacy is $100.

Total annual out-of-pocket cost for Emily's medicine under a PPO plan with no deductible and smaller copays: $1,200

List Price	$500	Deductible	$0
Manufacturer Rebates	$200	Copay	$0/mo
Net Price	$300	Co-insurance	$100/mo

- **Co-insurance costs:** $100 x 12 months = $1,200
  Paying 20 percent co-insurance that is based on $500 list price
- **Emily's total annual out-of-pocket cost:** $1,200 ($100 x 12 months)

Example 2: Chris

Chris gets health insurance through his state's exchange plan. Chris wanted the most affordable health insurance option, so he selected a plan with a high $2,000 deductible and lower monthly premiums.

When Chris goes to the pharmacy at the beginning of the year, he is still in his deductible period, so he must pay the full cost of his medicine upfront. Chris's insurer bases his medicine cost on list price, not the net price it negotiated with the manufacturer. For the first four months, until he reaches his deductible of $2,000, Chris must pay the full $500 list price of the treatment. Once his deductible is met, Chris's insurer covers the treatment for a monthly copay of $75.

Total annual out-of-pocket cost for Chris's medicine under a high deductible health plan: $2,600

List Price	$500	Deductible	$2,000
Manufacturer Rebates	$200	Copay	$75/mo
Net Price	$300	Co-insurance	$0/mo

- **Deductible costs:** $500 x 4 months = $2,000
  Paying full list price for medicine until deductible is met
- **Copay costs:** $75 x 8 months = $600
  After deductible is met, paying monthly copay set by insurer for remainder of year
- **Chris's total annual out-of-pocket cost:**
  $2,600 ($500 x 4 months + $75 x 8 months)

Example 3: Sydney

Sydney has health insurance through her employer. To balance premium and out-of-pocket costs, she chose a PPO plan with a moderate $500 deductible and slightly lower premiums.

When Sydney visits the pharmacy at the beginning of the year, she learns her insurance provider will not cover the specialty medicine her doctor prescribed until she tries a similar treatment, a common practice called step therapy. The similar treatment is in a lower tier, meaning her insurer likely pays a lower net price and therefore prefers that Sydney use this treatment. Because Sydney is in her deductible period, she pays the full list cost of the approved treatment, $500, for one month. When she reaches her deductible, her insurer covers her medicine in exchange for a flat $30 copay.

Sydney tries the insurer's preferred treatment for several months, but it doesn't manage her symptoms well, and her condition regresses. She has more doctor's visits and is evaluated by a specialist, all of which cost her additional money in the form of copays. After six months, Sydney qualifies for coverage of the originally prescribed treatment because she has tried and failed on the insurer's preferred treatment. Now she can get her treatment at the pharmacy for a flat copay of $30.

Total annual out-of-pocket cost for Sydney's preferred medicine under a PPO plan with moderate deductible and smaller premiums: $830

List Price	$500	Deductible	$500
Manufacturer Rebates	$200	Copay	$30/mo
Net Price	$300	Co-insurance	$0/mo

- **Deductible costs:** $500 x 1 month = $500
  Paying full list price of manufacturer's preferred medicine until deductible is met
- **Copay costs:** $30 x 11 months = $330
  After deductible is met, paying monthly copay set by insurer for remainder of year. Copay stays the same when Sydney switches back to her originally prescribed medication.
- **Sydney's total annual out-of-pocket cost:**
  $830 ($500 x 1 month + $30 x 11 months) **plus additional copays for doctor visits, lab tests, and a specialist evaluation**

Utilization Management and Cost Containment Tools

In addition to implementing benefit designs that shift more of a financial burden to patients, insurers employ various "utilization management tools" to contain the total amount they pay for medicines. Aimed at steering patients to lower-cost therapies, utilization management tools include:

- **Prior authorization requires doctors to obtain approval** from an insurer before a patient can receive a particular medicine. Prior authorization helps make sure patients get the insurer-preferred medicine, but the practice can result in delays that cause some patients to forego their treatment altogether.
- **Step therapy requires patients to try medicines on an insurer's preferred list of prescriptions** before the insurer will cover the cost of another medicine. Step therapy is also known as "fail first."
- **Non-medical switching happens when insurers eliminate coverage for a patient's current medicine,** switching them to treatment that has a lower cost for the insurer. While some patients can switch to a different treatment without issue, this practice can be harmful to some patients, especially those with complex, chronic, or rare conditions, who have found that one medication works better than another.
- **Accumulator adjustment programs prevent savings cards offered by pharmaceutical manufacturers from applying** toward patients' out-of-pocket maximums or deductibles. When an accumulator adjustment program is in effect, patients may be surprised to learn that the reduced out-of-pocket costs they've been paying—thanks to their savings card—are not counting toward their deductible or out-of-pocket maximum. This can result in additional and unexpected costs for the patient, which make it harder for patients to stay on their medications.[104]

Physicians find that these tools can interfere with their ability to deliver care. In a survey of physicians, 91 percent of respondents reported that prior authorization delayed patient access to necessary care and had a significant or somewhat negative impact on patients' clinical outcomes.[105] Regarding step therapy, 90 percent of primary care physicians report that it is a serious issue with respect to their ability to deliver quality care to patients.[106] Patients have expressed dissatisfaction with non-medical switching. In a survey of patients, approximately 70 percent of respondents reported that when they were switched to different medications for non-medical reasons, those medications were less effective than the drugs they had been on.[107] In another survey, 40 percent of patients reported that frustrations with non-medical switching led them to stop taking their medicines altogether.[108] ■

OUR POSITION ON NON-MEDICAL SWITCHING: OUR FIRST RESPONSIBILITY IS TO OUR PATIENTS

We believe treatment decisions belong in the hands of patients and their healthcare professionals, which is why we are concerned about clinically stable patients being switched to other therapies for non-medical reasons.

Because our first responsibility is to patients who use our medicines, we oppose non-medical switching even when it works to our advantage—as in instances where, for a given condition, a Janssen medicine is the lowest-cost therapy on a payer's formulary. We do not proactively seek arrangements with payers that require patients who are clinically stable on a medicine to switch to a different medicine.

FREQUENTLY ASKED QUESTIONS (FAQ)

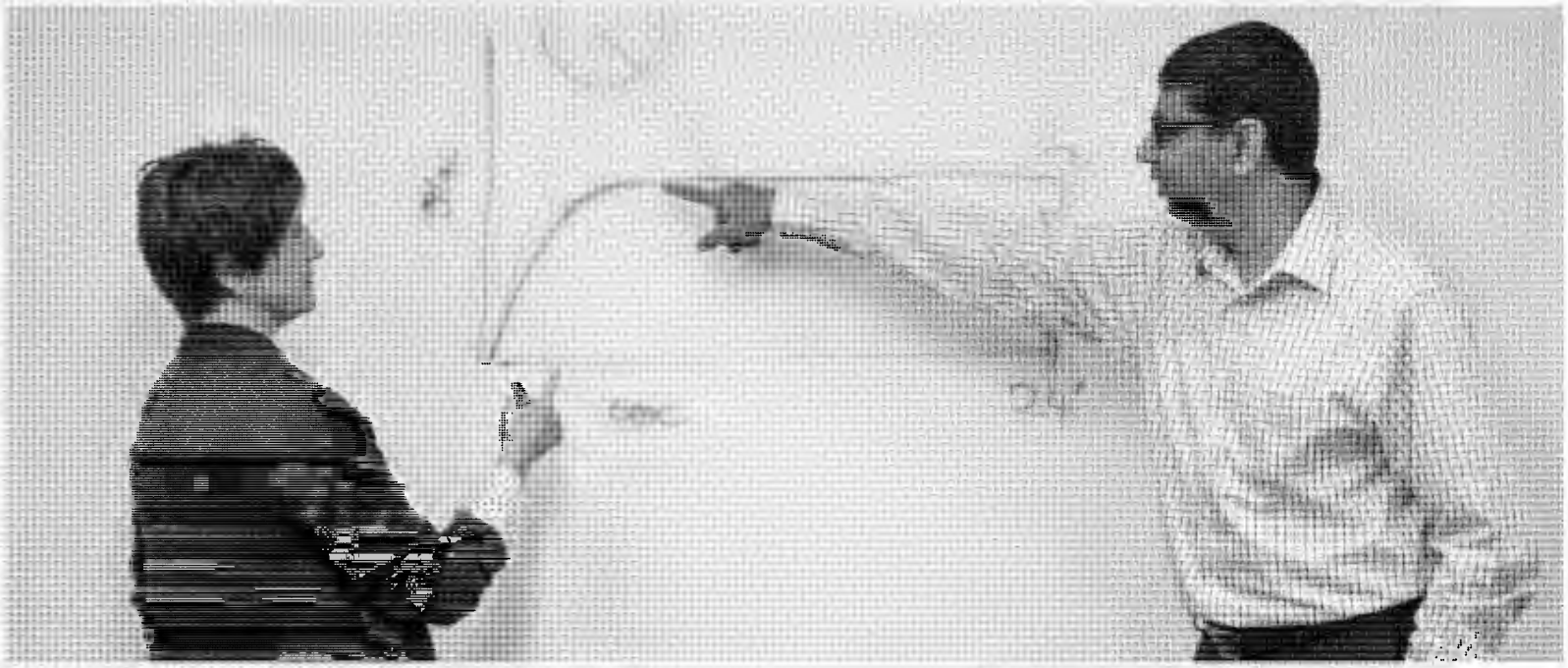
Why does Janssen increase the prices of medicines?

Many factors contribute to price increases. After we receive FDA approval, we continue to conduct research on our medicines, including studies to understand how the medicines work in a real-world setting. We continue to monitor for safety and to secure regulatory approval for new indications, dosages, or improved product formulations—investments that enhance the value of our medicines for patients and society. Additional regulatory requirements, upgrading or building new manufacturing facilities, an increase in the cost of goods, and other market dynamics also play a role. And finally, we must continue to generate returns to invest in R&D.

Biopharmaceutical innovation paves the way for the introduction of generic medicines, which enables medicine costs to be reduced over time. In the U.S., medicines lose market exclusivity, on average, about 12 years after they are introduced.[71] When that happens, prices generally drop significantly—an average of 90 percent within two and a half years for oral generic medicines[72]—giving patients ongoing access to effective therapies at a lower cost.

Do medicine price negotiations occur in Medicare?

Yes. Pharmaceutical companies negotiate rebates on medicines purchased by Medicare through the Part D benefit and through Medicare Advantage plans. Negotiations occur with private health insurance companies and PBMs that administer benefits for these public programs. The payers that administer Part D benefits represent as many as 40 million covered lives,[73] meaning they are powerful negotiators with leverage to secure large discounts and rebates.



Continued on next page »

FREQUENTLY ASKED QUESTIONS (FAQ)

Negotiation also takes place in Medicare Part B, albeit indirectly. The Part B benefit generally covers outpatient services received at a hospital, doctor's office, or clinic, including medicines that are injected or infused. The price that Medicare Part B reimburses is based on a calculation known as the Average Sales Price (ASP). ASP is the weighted average of all manufacturers' sales prices, net of rebates and discounts. As a result, prices in Medicare Part B reflect aggressive market-based negotiations in the private, competitive market. In recent years, this market-based model has delivered multiple breakthrough drugs and biologics—therapies that are improving and saving the lives of U.S. patients every day.

Why do U.S. medicine prices differ from prices in other countries?

We are sometimes asked why patients in the U.S. pay more for medicines than patients in other countries. In fact, most cross-country comparisons focus solely on the list prices of medicines and do not account for the significant discounts required for participation in U.S. public programs, such as Medicaid, the 340B Drug Discount Program, and the Federal Supply Schedule (for U.S. Department of Veterans Affairs and Department of Defense), as well as the discounts and rebates negotiated by private payers. For this reason, most of these international comparisons are not "apples to apples."

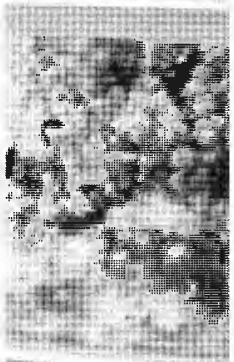
In the U.S., we have a market-based system that provides financial incentives for innovation while managing access and cost through intense competition, payer negotiations, and the high use of generics. In other countries, medicine prices are achieved through national regulation, which often restricts or delays access to innovative medicines and limits patient and physician choice. For example:

- Compared to patients in the U.S., the typical wait time for patients in five European Union countries to gain access to cancer medicines ranges from seven months to a year and a half longer.[32,33]
- Of 45 cancer medicines approved by the FDA from 2009 to 2013 and available through Medicare, only 58 percent were made available by government health authorities in the U.K., 42 percent in France, 29 percent in Canada, and 24 percent in Australia.[34]
- In three major developed countries outside the U.S., it took one of our breakthrough medicines for multiple myeloma approximately 22 months to reach patients after local approval. In some cases, negotiations are still ongoing. Government reimbursement for another breakthrough medication for B-cell cancers took 12 months to nearly three years longer in those same major developed countries.

ADVANCING A BETTER WAY

WE BELIEVE GOOD **HEALTH** IS AT THE **HEART OF HUMAN** PROGRESS. Together, our **challenge is to** develop a **healthcare system** that delivers what all of us want: **greater access to** care at more **manageable** cost and, most **importantly,** better health for all.

Ensuring that every **American** has access to **affordable healthcare**, including the medicines they need, **means** changing how **we pay for medical** care. Our current system rewards **the quantity** or volume of **care delivered**, regardless of results. Shifting to an **approach that prioritizes value rather than** volume means that everyone who plays a role in the **healthcare system is held** accountable for the **results** or outcomes they deliver, including **pharmaceutical** manufacturers like **Janssen. This** approach prioritizes healthcare interventions—whether medicines, **surgeries,** in-office **visits**, or other forms of care—**that** deliver the best results at the **lowest** possible cost. By spending less **on care that doesn't work**, we will have **more** to spend **on care** that does, now and in the **future. Greater efficiency today** also promises **more innovation** tomorrow as well as more **affordable access to that innovation.**



BY THE NUMBERS: THE VALUE OF MEDICINES

Reduction in direct medical costs attributable to cardiovascular medicines like statins:
27%[115]

Amount of potential savings from correct use of medications for chronic conditions:
$213 billion[116]

Total healthcare dollars spent on medicines:
14%[117]

Decline in cancer deaths between 1991 and 2016:
An overall decline of 27%
in 25 years, meaning an estimated 2.6 million fewer cancer deaths than expected if death rates had remained at their peak.[118]

For patients with early-stage HIV, lifetime cost savings after the introduction of antiretroviral therapies:
$402,000[119]

Percentage of prescriptions that are for generic medicines:
90%[120]

Proportion of recent gains in life expectancy attributable to medicines:
70%[121]

Assessing the Value of Our Medicines

Part of being accountable for the value we deliver means being transparent about how we assess the value we bring to patients and to the healthcare system more broadly. When we assess the value of our medicines, we follow four principles:

1. **What matters most in determining a medicine's value is its impact on patients.[122]**

   First, we look at a medicine's clinical profile—its effectiveness, ability to improve health-related quality of life, tolerability, side effects, etc.—compared with alternative treatments for the same condition or disease. We also look at how the medicine will be administered and in what clinical setting, the length or difficulty of the regimen, and whether the treatment requires any diagnostic tests—all factors that matter to patients. We consider the importance patients and their families place on having additional months or years of life; being able to avoid disability, hospitalization, and extensive medical procedures; and not having to depend on others for daily care. And because patients respond differently to different medicines, even those within the same class, we think about the benefit of having a variety of treatment options from which to choose.

2. **The value of a medicine should include its impact on the healthcare system and society.[123]**

   Medicines have effects that go beyond patient health. They can generate healthcare savings by reducing the need for future doctor visits, emergency room use, hospitalizations, nursing home stays, and procedures or operations. Medicines can add value to the broader society by improving workplace productivity, reducing disability, and preventing health-related interruptions in work or education. And in cases of serious mental illness like schizophrenia, some medicines can delay or reduce relapses, which may result in less frequent use of law enforcement or justice system resources.[124]

3. **Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the healthcare system, and society.[125]**

   Some medicines have an immediate benefit that lasts a lifetime. Some medicines significantly extend a lifetime. Others have a more moderate benefit or a benefit over a shorter period. Our assessment of a medicine's value considers the time needed to fully realize all of its outcomes for all stakeholders, not just the first few months or a year or two.

4. **Evidence considered in assessing the value of a medicine should be high-quality, current, and relevant.[126]**

   We evaluate clinical trial data and real-world evidence from a variety of sources, including academic medical centers, government agencies, and healthcare systems, as well as from our own research. Evidence can vary in quality and reliability, which is why for everything we evaluate we

strive to confirm its credibility, identify ambiguities, and determine how best to address differences in conclusions. Some evidence is available immediately, while other evidence becomes available only after a longer period of time. Quality evidence, regardless of its source, makes clear the study methods, assumptions, and limitations, and it is transparent about any uncertainties in the data.

FAST FACT

When we assess the value of our medicines, we follow four principles:

1. What matters most in determining a medicine's value is its impact on patients.[129]

2. The value of a medicine should include its impact on the healthcare system and society.[130]

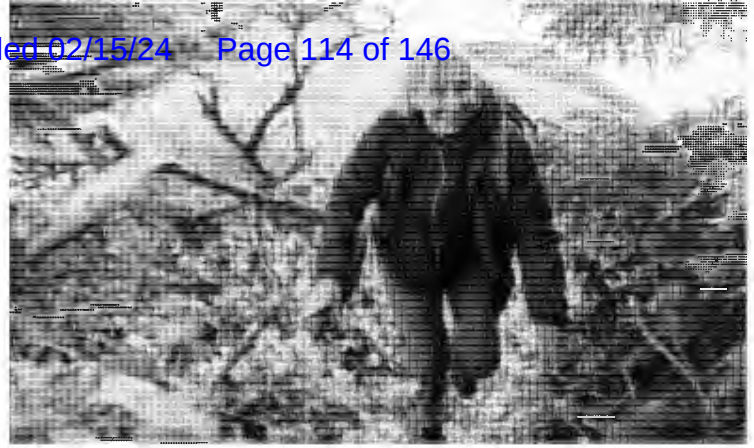
3. Treatment outcomes should be assessed over an appropriate timeframe to capture all the benefits and risks for patients, the healthcare system, and society.[129]

4. Evidence considered in assessing the value of a medicine should be high-quality, current, and relevant.[130]

Value Frameworks

Measuring and defining the value of medicines has been the subject of much discussion. In the U.S., several organizations have introduced frameworks and methodologies to assess the relative value of medicines.[131] These approaches, or "value assessment frameworks," can supply useful perspectives on the value of medicines. However, many of the current frameworks fail to include factors that are critical to fully assessing value. No single framework captures the complete range of factors that makes a medicine valuable.

Most of these frameworks consider important measures like how well the medicine works compared to other existing treatments and how much the medicine drives down more costly forms of healthcare spending. But some



take a short-term view of value. For example, they consider only the period in which the patient is being treated or the time it takes to see if a treatment is working, both of which fail to reflect the full benefits a medicine can provide to a patient over a lifetime.[132] And some frameworks focus heavily on the impact a medicine has on healthcare budgets, not on the value it brings to individual patients, their families, or society.[133]

Most importantly, value assessment frameworks need to measure value according to factors that truly matter to patients. These include improved quality of life, the ability to be productive at work, or the chance to remain independent for a longer period of time. These types of factors are not reflected in many of the current value frameworks.[134]

Value assessment frameworks are still evolving, and developers should address these and other important limitations before they are widely adopted in healthcare decision making. Doing so will allow us to have more informed conversations about health system costs and the respective value of healthcare interventions, including medicines.[135, 136]

Another consideration is that advances like personalized medicines and gene and cell therapies have the potential to dramatically reduce the burden of—and even cure—serious, life-altering, or life-threatening diseases. As these treatments become available, it is critical that evaluation of their clinical benefits and potential to offset costs over the long term remain independent of discussions about their immediate impact on the budgets of health systems. It is also important to strive to accelerate the access to these life-changing therapies as the FDA has done through approaches meant to make such medicines available as quickly as possible, such as Accelerated Approval.

We look forward to working with developers of value frameworks to improve their usefulness in healthcare decision-making and, importantly, to help ensure they reflect appropriate value principles.

REAL-WORLD VALUE AND EVIDENCE

To better understand and show the value our medicines bring to patients and the healthcare system, we generate clinical information on the use, risks, and benefits of a medicine derived from data on how a medicine is being used in the real world, outside of a clinical trial. Known as "real-world evidence" this data allows us to see how our medicines effect people in their everyday lives and gives us a more complete view of the safety and effectiveness of our medicines. Through real-world studies, we have shown that our medicines can:

Improve long-term health outcomes.

Patients taking our medicine for diabetes were less likely to stop taking the medicine as prescribed, to change to another medicine, or to need a second medicine in order to achieve the desired health outcome. This is important because adherence—taking a medicine as prescribed—can result in better long-term health outcomes.

Reduce costs to healthcare systems.

Patients taking one of our medicines for schizophrenia were hospitalized less frequently than patients taking different medications for the same serious mental illness. The reduced rate of hospitalizations produced savings of greater than $8,500 per patient per year for the healthcare system that partnered with us on this research.[9]

Better manage side effects.

We found that patients who began treatment with one of our medicines for Crohn's disease were able to decrease use of the corticosteroids and opioids often prescribed to manage symptoms—treatments that come with significant side effects. By analyzing an anonymized database of health records of patients with Crohn's disease, we found that within eight weeks of being treated with one of our medicines, patients' use of opioids and steroids decreased.

Reduce costs to patients.

For patients with HIV, we know starting anti-retroviral therapy (ART) immediately after diagnosis leads to better health outcomes. What we didn't know was whether cost would prevent payers from adopting this clinical best practice. When we analyzed Medicaid databases in six states, we found that patients who started ART immediately had better health outcomes as well as lower costs for care. As it turned out, the best treatment was also the most economical.

A Value-Based System

As we work to more clearly define and measure the value of our medicines, we are taking steps to advance a more results-based approach in three distinct ways: through the establishment of innovative contracting models, also known as value-based contracts; through partnerships that explore value-based care models; and through population health research that seeks to address quality and cost challenges in today's healthcare system.

FAST FACT

Janssen is advancing a more results-based approach through:

Innovative Contracting Models

Value-Based Partnerships

Population Health Research

Innovative, Value-Based Contracting Models

An important part of the shift to a value-based system is innovation in the way contracts between payers and manufacturers are structured. By creating common incentives to deliver value for patients, innovative contracting models can provide better outcomes at lower costs.[58] They can take a variety of forms, including:

- **Contracts tied to measurable medical outcomes:** In this type of contract, the pharmaceutical company and payer agree on a measurable medical outcome that both parties are trying to achieve. The contract is based on achieving this shared goal, which would result in beneficial outcomes for the payer's patient population. If the medicine doesn't meet the goal, the pharmaceutical company will pay a rebate to the insurer.
- **Contracts to help insurers better predict costs:** Pharmaceutical companies might cover unexpected costs of providing a medicine to a patient. For example, if a patient needs a higher dose of a medicine than the average patient, the pharmaceutical company might agree to cover part of the cost of the additional medication. This type of arrangement allows insurers to better anticipate costs and manage risk over a large population of patients and, as a result, enables them to provide better access to that medicine.
- **Contracts tied to offsets of other healthcare expenditures:** The insurer provides better access to a medicine with the expectation the medicine will reduce the need for other costly healthcare interventions, such as surgeries, physician visits, and hospital stays. If such healthcare expenditures are reduced, the pharmaceutical company is paid more; if they increase, the pharmaceutical company agrees to provide more rebates.

We are enthusiastic about the potential for expanding the use of innovative value-based contracting models. Nevertheless, a number of technological and policy barriers can make these agreements challenging to implement. To address technological barriers, we advocate for modernizing our healthcare data system to make it easier to track patient outcomes. To address policy barriers, we support the following approaches: establishing safe harbors to better enable manufacturers to partner with payers and share risk; clarifying the treatment of value-based contracts in government price calculations, including in the complex Medicaid Best Price determination; and making comparative formulary and cost-sharing information readily available so patients have the information they need to make better decisions.

Examples of Janssen's Value-Based Contracts

We have established several innovative, value-based contracts with insurers and continue to explore new opportunities. Here are some examples:

- **Immunology:** In 2018, Janssen partnered with payers to create an agreement in which the price of a medicine for chronic immune conditions varies based on how well it works for patients. Immune conditions often require long-term treatment with a medicine. The agreement measures how long patients who are newly treated with an immunology medicine stay on treatment. If they stop treatment, we return a portion of the cost of that treatment to the payer. In this case, treatment duration is being used in lieu of an outcomes-based measurement of efficacy.
- **Oncology:** We have partnered with public and private payers on novel contracts for patients with prostate cancer. In one contract, we agreed to provide additional rebates to the insurer for plan members who meet eligibility criteria and whose treatment duration is shorter than a predetermined period of time. Similar to the immunology example above, the insurer receives a price concession if the patient stops treatment.
- **Diabetes:** We have partnered with a leading payer on a contract under which we are paid more if data show our medicine that treats adults with type 2 diabetes contributed to lowering other identified healthcare costs, such as the use of additional medicines. If those costs increase, we pay additional rebates. We have also partnered with several payers on results-based contracts tied to clinical outcomes for that medicine. Under such agreements, we provide additional rebates if the agreed-upon health outcome is not achieved.

Value-Based Partnerships

Beyond value-based contracts with payers, we continue to participate in partnerships to explore value-based care models with others in the system. For example, we are pleased to support a multi-stakeholder effort established by Value Based Insurance Design (VBID) Health. This is an effort to identify, measure, and eliminate low-value healthcare services—defined as care that yields few benefits but comes with a high cost. Value-based insurance design bases patient out-of-pocket costs on the value of medical services, favoring the high-value care that provides important benefits (clinical or societal) relative to their cost. In other words, underused but high-value services have lower out-of-pocket costs, while overused but low-value services have higher out-of-pocket costs. Value-based insurance design has the potential to improve patient adherence to medicines and lower costs. For example, the state of Connecticut implemented value-based insurance design for its employees who opted in, raising copays for low-value services like non-emergency visits to urgent care and eliminating them for routine doctor visits related to chronic conditions. It eliminated copays for diabetes medication and eliminated or lowered them for medications used to treat asthma, COPD, heart disease, hypertension, and hyperlipidemia. As a result, use of high-value services and adherence to medications for chronic conditions increased, and emergency room visits decreased.[139]

Population Health Research

We are also working to advance results-based healthcare at the population level. In an effort to contribute to the "Triple Aim" goals of improving patient care and population health while improving efficiency,[140] our Population Health Research team is engaged in a number of research partnerships with a variety of healthcare stakeholders to find evidence-based solutions to population health challenges. Here are some examples:

- **Hospital readmissions are a significant health system cost driver.** We collaborated with Sharp Healthcare to use real-world data to better understand how to proactively identify patients at higher risk for readmissions.
- **Costs to the healthcare system are also driven by hospital use and emergency room visits** that could have been prevented by lower-cost interventions and the early delivery of primary care. We are working with a large regional health system in northern California to understand "super-utilizers"—the 5-10 percent of high-need, high-cost patients who use a disproportionate number of healthcare services. These patients often have multiple chronic illnesses and complex psychological and social needs.[141, 142] We are trying to understand how these patients are impacted by serious mental illness.[143] This research can help identify at-risk patients and inform the design of interventions that improve patient health.
- **Type 2 diabetes is a chronic** and progressive **disease.** Patients with type 2 diabetes often do not reach recommended HbA1c targets, a measure of diabetes control. In partnership with researchers at the University of Utah and SelectHealth, the insurance division of Intermountain Healthcare, we identified a broad set of patient factors associated with failure to achieve HbA1c goals. This analysis of real-world data will enable better identification of high-risk patients and help guide patient care and physician education.
- **We have entered into a research study with Apple Inc.** to investigate whether a new heart health program can accelerate the diagnosis of atrial fibrillation (AFib) and improve health outcomes for the approximately 33 million people living with the condition,[144] which can lead to stroke and other devastating complications. Using an app from Johnson & Johnson in combination with Apple Watch's irregular rhythm notifications as well as its ECG app, the study aims to analyze the impact of Apple Watch on the early detection and diagnosis of AFib. A multi-year research program will begin later in 2019. AFib is responsible for approximately 130,000 deaths and 750,000 hospitalizations every year in the U.S. alone.[145]

We are also investing in improving population health and quality in the health system at large. We sponsored the National Committee for Quality Assurance's

(NCQA) Population Health Management Resource Guide,[146] a tool to support health plans in implementing best practices for achieving their population health management goals. The guide lays out five elements of a population health strategy that plans can use to improve the overall health of their members.

We are engaged in these efforts because we believe a more value-based healthcare system has tremendous potential to improve patient health, increase access to care, and curb the increase in healthcare spending. The transition to this value-based approach will require pharmaceutical companies, payers, providers, and policy makers to work together, and we will continue to look for ways to help lead in this effort. ■

CONTRIBUTING POLICY SOLUTIONS FOR A BETTER WAY

We have a long history of contributing policy ideas and working with policymakers on both sides of the aisle to find practical solutions that maintain what's distinctive about American healthcare: access to innovative therapies, personal choice, and doctors and patients making decisions based on what is right for each individual. Guided by the belief that policy solutions should first and foremost aim to improve healthcare for patients, we consider the following principles in evaluating and developing policy proposals:

- **Access.** Policies should support broad patient access to appropriate, affordable, and high-quality treatment options.
- **Choice.** Policies should safeguard the physician-patient relationship and keep treatment decisions in the hands of patients and their healthcare professionals; and clinically stable patients should not be switched to other therapies for non-medical reasons.
- **Patient Safety.** Policies should ensure patient safety by applying consistently rigorous clinical and manufacturing quality standards.
- **Sustainability.** Policies should lower overall costs to the system while sustaining a biomedical research ecosystem that continues to deliver transformative medical advances.

When the government asks for ideas about how to improve the healthcare system, we share our perspective and provide practical solutions based on the principles above. Amid the current conversation about healthcare spending in the U.S., the Administration has issued calls for ideas to reduce medicine prices. We have actively responded with solutions. Below are examples of the solutions we've offered in the specific policy areas the Administration is focused on:

Reducing Patient and Program Costs in Medicare Part B

The Administration has sought policy ideas to reduce costs in Medicare Part B while minimizing disruption to the supply chain and eliminating potential financial incentives for high-cost drugs.

In response, we crafted a policy solution to address these incentives while maintaining patient access to appropriate treatments. Under our

model—participation in which would be voluntary—Medicare would reduce Part B acquisition costs and reimburse all stakeholders for the value of the services they provide. Our solution leverages the benefits of the existing ASP mechanism, which captures the savings of open competition and should continue to play a role in any reform.

Critically, any Part B reform must also maintain the levels of access and innovation that are crucial for patients today and in the future. Part B covers medicines that treat diseases that are often irreversible, progressively damaging, or life-threatening. At the same time, innovations in development promise treatments for diseases once thought beyond cure. Access to all current and future Part B medicines is therefore paramount, as is fostering conditions that support continued medical advances.

Continued on next page ▸

CONTRIBUTING POLICY SOLUTIONS FOR A BETTER WAY

Capping Patient Out-of-Pocket Costs in Medicare Part D

While Medicare Part D is working for many seniors and has been effective in containing costs, we believe a cap on patient out-of-pocket costs in Medicare Part D is a needed protection. Without a cap, Medicare beneficiaries face unlimited out-of-pocket expenses, and, as research shows, high out-of-pocket costs reduce patient adherence to prescribed treatments and make them more likely to abandon their prescriptions.[147] Poor patient outcomes related to lack of adherence or abandonment of prescribed treatments can lead to an increase in overall healthcare costs.[148]

Individual and group health insurance policies are already required to have out-of-pocket caps. Medicare, which serves some of the sickest and most vulnerable patients, should also have that protection. We support policy approaches that would make it possible to implement an out-of-pocket cap in a fiscally responsible way without creating new costs or access barriers for patients.

Rebate Reforms

Too often the rebates and discounts pharmaceutical manufacturers negotiate are not directly shared with the patients who use the medicines for which they are provided, leaving the sickest patients paying higher out-of-pocket costs to subsidize those who are healthier. This is not how health insurance is supposed to work. A competitive marketplace should deliver lower out-of-pocket costs to patients. To ensure it does, we support reforms to the system of incentives currently in the supply chain.

We anticipate eliminating rebates could result in lower list prices, provided these rebates and discounts are not replaced with equally high fees or other payments. As reforms take shape, we also strongly advocate that beneficiary copays be based on the final price payers receive from manufacturers.

Altering the current rebate structure would be a major change to the entire pharmaceutical supply chain. In order to minimize disruption for patients, any change should be implemented thoughtfully. We look forward to providing ongoing feedback should the Administration put these changes into effect.

Transparency in Direct-to-Consumer (DTC) Advertising

Consumers deserve to better understand what they can expect to pay out-of-pocket for their medicines. When including list price information in DTC TV ads was proposed in the American Patients First blueprint, we embraced the challenge to think about what additional transparency around medicine costs would benefit patients. After listening to

patients and consumers, we are introducing a common-sense approach to share meaningful and relevant information about medicine costs. We will begin to voluntarily include the list price and typical patient out-of-pocket costs in our U.S. pharmaceutical TV advertising, starting with our most frequently prescribed medicine, XARELTO®. This approach builds on our legacy of leadership in transparency and on our commitment to the PhRMA DTC Advertising Principles. (For more about our DTC advertising, please see the "Pricing & Patient Costs" chapter.)

We stand ready to continue to offer solutions to the Administration and other stakeholders as the conversation continues about how to reduce healthcare costs while improving the quality and efficiency of care for patients.

RESOURCES FOR PATIENTS

PATIENTS SHOULD HAVE AFFORDABLE ACCESS TO MEDICINES.

In the previous chapter, we discussed how we negotiate with insurers to support the availability of our medicines. We also help patients obtain appropriate access to our medicines, because we know that insurance coverage can be complicated and finding financial assistance can be challenging.

In this chapter, we describe the resources we provide to patients, caregivers, and healthcare providers through our Janssen CarePath program. We also include information about our support for charitable organizations and foundations that help patients get the medicines they need.

While we recognize these programs are not a long-term solution for all patients, they are one way we strive to meet the needs of the patients we serve and the healthcare professionals who care for them.

Janssen CarePath

Even with health insurance, some patients face high prescription medication out-of-pocket expenses. Others are limited in the types of medicines they can access due to medication management measures like prior authorization and step therapy. (See "Utilization Management and Cost Containment Tools" in the "Pricing and Patient Costs" chapter for more information.) For patients facing these challenges, we've created some tools to help.

Janssen CarePath provides access, affordability, and treatment support resources to help patients get started on, and stay on, the Janssen medications their healthcare providers prescribe. Janssen CarePath Care Coordinators offer various forms of patient access support: they answer questions about insurance coverage for Janssen medications and potential patient out-of-pocket costs; locate nearby treatment centers for certain medications; provide resources to help patients take the Janssen medications as prescribed; and, if needed, identify options that may help make the medications more affordable. These resources are available for patients who are prescribed Janssen products in the following therapeutic areas: cardiovascular and diabetes, dermatology, gastroenterology, infectious diseases, neuroscience, oncology, and rheumatology.

For commercially insured patients who meet the program requirements, we also offer our Janssen CarePath Savings Programs to reduce patient out-of-pocket medication costs. Such programs—sometimes referred to as "copay cards" or "copay coupons"—are an important tool for helping patients gain access to the medicines prescribed by their healthcare provider. Copay coupons continue to play a critical role in making out-of-pocket costs more manageable for patients.[149]

Janssen CarePath also helps healthcare providers focus their time on treating patients. For healthcare providers, navigating complex insurance benefits adds to their administrative burden. According to a survey by the American Medical Association, physicians and staff spend more than 16 hours a week seeking pre-approval from insurers to prescribe medicines—also known as prior authorization—from insurers, with 75 percent of physicians saying requests impose a "high" or "extremely high" burden.[150] Janssen CarePath helps by verifying patients' health insurance benefits to make sure providers are familiar with their patients' coverage for Janssen medicines and any requisite prior authorization, step therapy, or other payer policies.

In 2018, we helped approximately 1 million patients through the Janssen CarePath program.[151] This includes approximately 550,000 commercially insured patients who reduced their out-of-pocket expenditures through the Janssen CarePath Savings Program.[152]

WHY WE CAN'T OFFER COPAY CARDS TO SENIORS

The Social Security Act restricts the kinds of benefits pharmaceutical manufacturers can provide patients enrolled in federal and state-subsidized healthcare programs, including Medicare. Savings card programs are one such restriction. As a result, only patients who are privately and commercially insured are eligible for pharmaceutical savings cards.

While we can't help seniors through savings program cards, we contribute to foundations and independent charitable organizations that can assist seniors with medication-related copays. (See more information on our charitable contributions later in this chapter.)

In addition, Medicare patients may be eligible for one or more programs not affiliated with Janssen, such as the Medicare Savings Program, Medicare Extra Help (Part D), and state-sponsored programs. More information is available at medicare.gov.

MEET OUR JANSSEN CAREPATH COLLEAGUE

GINA GIORDANO

Director of Patient Access Solutions for Oncology

MANY PATIENTS FACE HIGH OUT-OF-pocket costs and understanding their health insurance coverage for medicines can sometimes be difficult. As mothers, fathers, caregivers, and patients ourselves, we understand the challenges our patients may face, and we're poised to listen and to provide the best experience we can.

Gina Giordano helps patients who have been prescribed Janssen medicines start and stay on their medicine. Her goal is to empower patients to take their medication as their healthcare provider prescribed.

"Many patients face high out-of-pocket costs and understanding their health insurance coverage for medicines can be difficult," said Giordano. "As mothers, fathers, caregivers, and patients ourselves, we understand the challenges our patients may face, and we're poised to listen and to provide the best experience we can."

Janssen created a one-stop shop for patients called Janssen CarePath. The dedicated Care Coordinators try to simplify the process by showing patients the programs that are most likely to help, given the patient's coverage and financial situation. For example, commercially insured patients may be able to use the Janssen CarePath Savings Program to help reduce their out-of-pocket costs for Janssen medications. The program also offers resources and information to patients that help them understand their condition and take their medications as their physician has prescribed, including treatment reminders and information on where infusion centers are located.

To learn more, please visit janssencarepath.com or call 1-877-CarePath.

Independent Program and Foundation Support

We also support independent programs and foundations that help patients in the U.S.:

- **We donate medicines and funding to the Johnson & Johnson Patient Assistance Foundation, Inc.**, an independent, nonprofit organization that is committed to helping eligible patients without insurance coverage receive prescription products donated by Johnson & Johnson operating companies. More information about the Johnson & Johnson Patient Assistance Foundation is available at jjpaf.org or by calling 1-800-652-6227.

  In 2018, we donated approximately $1 billion[153] in free product and financial support to the Johnson & Johnson Patient Assistance Foundation, enabling the Foundation to provide medicines at no cost to approximately 76,000 patients.[154]

- **We also make financial donations to independent charitable foundations** that assist underinsured and financially needy patients with treatment-related expenses.

  In 2018, we donated approximately $200 million to independent charitable foundations,[155] enabling them to assist an estimated 30,000 patients with medication-related copays for any physician-prescribed medicines that treat certain diseases covered by the foundations.[156]

Other Patient Programs and Resources We Support

In addition to the programs described above, patients and providers should be aware of the many other resources available to help patients access medicines. Some include:

The Partnership for Prescription Assistance (PPA): This organization helps patients who are uninsured or underinsured access the medicines they need through a program that is right for them. Since 2005, PPA has helped more than 10 million people get their prescriptions for free or nearly free.[157] Visit pparx.org to find out whether PPA can help you or someone you know.

Healthcare Ready: Through collaboration between the public health and private sectors, Healthcare Ready helps address pressing health issues before, during, and after major natural disasters. Visit healthcareready.org to learn about the resources that may be available to help those affected by hurricanes and other natural disasters. ■

REQUESTS FOR ACCESS TO MEDICINES IN DEVELOPMENT

Pre-approval Access Programs (also known as Expanded Access or Compassionate Use)

Pre-approval access (PAA) is the overarching term used at Johnson & Johnson for access to an investigational medicine outside of a clinical trial and prior to health authority approval. The main pathway for gaining access to Janssen's investigational medicines is for a patient to enroll in a clinical trial.

For patients with serious or life-threatening illnesses who cannot enroll in clinical trials, pre-approval access programs, such as "expanded access" programs and "named patient" programs for multiple patients, or "single-patient access" requests for individual patients, can be considered.

Our policy for considering pre-approval access to investigational medicines is grounded in key ethical principles, including:

1. All requests for pre-approval access are considered in a fair and just manner;
2. Sufficient understanding of the potential benefits and risks of the investigational medicine has been established through the conduct of a rigorously designed, scientifically and medically sound clinical trial program;
3. Patients are not put at risk of unnecessary harm;
4. Fulfillment of pre-approval access will not jeopardize the clinical trial program that may lead to broader public access through marketing authorization; and
5. Fulfillment of pre-approval access fully complies with applicable laws and regulations.

We typically consider making pre-approval access available when our clinical studies are complete, or sufficient scientific evidence is available to inform careful review of requests prior to health authority approval.

The list of agents available for evaluation in the pre-approval setting for the Janssen Pharmaceutical Companies of Johnson & Johnson can be found at clinicaltrials.gov. For more information on our pre-approval access program and policy, please visit janssen.com/compassionate-use-pre-approval-access.

The Compassionate Use Advisory Committee (CompAC)

The Compassionate Use Advisory Committee, or CompAC, is a group of global external advisors that provide a fair, ethical evaluation of our plans to consider and support potential pre-approval access requests, including "single patient access" requests. Developed in collaboration with New York University Langone Health, CompAC facilitates the review of compassionate use requests by an independent, external body of internationally recognized medical experts, bioethicists, and patient representatives. After a successful pilot that began in 2015, CompAC was expanded to include additional investigational medicines in development at Janssen.

For each single-patient (compassionate use) request, our physicians conduct an initial review to identify patients who may be immediately eligible for a clinical trial or "expanded access" and "named patient" program, and they direct those requests accordingly. If a patient has exhausted all available treatment options and does not qualify for any established clinical trial or pre-approval access program, the request will be assessed internally according to pre-established criteria which have been approved by CompAC. Some cases may also be forwarded to CompAC based on these pre-established criteria. CompAC evaluates such requests and provides a recommendation to Janssen. A Janssen physician makes the final decision on patient access for all compassionate use requests.

In 2018, Janssen provided access to 717 patients via single-patient request and named patient programs.[158]

How to Get More Information

The best and fastest way to get more information on how to access Janssen investigational medicines, or to submit a request for access is for the patient's physician to call 1-800-JANSSEN or email janssenmedinfo@its.jnj.com. For information about how we process requests, please visit janssen.com/compassionate-use-pre-approval-access.

REFERENCES

1. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.
2. Figure according to Janssen internal financial accounting.
3. Ibid.
4. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
5. Data is an approximate number of patients supported by Janssen CarePath provided by the program administrator. In previous years this data included patients helped through Janssen CarePath separately from JANSSEN CONNECT®. In 2018, we expanded the Janssen CarePath program offerings to include resources previously provided under JANSSEN CONNECT®.
6. Ibid.
7. Wamble, David, Michael Ciarametaro, Katherine Houghton, Mayank Ajmera, and Robert W. Dubois. "What's Been the Bang For The Buck? Cost-Effectiveness of Health Care Spending Across Selected Conditions In The US." Health Affairs Vol 38., No 1.
8. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
9. Figure according to Janssen internal financial accounting.
10. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "NDA and BLA Approval Reports – New Molecular Entity (NME) Drug and New Biologic Approvals." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm372420.htm.
11. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "Novel Drug Approvals for 2018." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm. Notes: Number reflects NME approvals achieved by current Janssen Pharmaceutical companies.
12. The YODA Project. "Summary of Data Inquiries and Requests." http://yoda.yale.edu/table-3-data-requests-approved.
13. Figure according to Janssen internal financial accounting.
14. Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC).
15. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.
16. Data is an approximate number of patients supported by Janssen CarePath provided by the program administrator. In previous years this data included patients helped through Janssen CarePath separately from JANSSEN CONNECT®. In 2018, we expanded the Janssen CarePath program offerings to include resources previously provided under JANSSEN CONNECT®.

REFERENCES

Our Investments

17. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
18. PricewaterhouseCoopers. 2018 Global Innovation 1000 Study. https://www.strategyand.pwc.com/innovation1000.
19. Figure according to Janssen internal financial accounting.
20. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
21. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "NDA and BLA Approval Reports – New Molecular Entity (NME) Drug and New Biologic Approvals." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm3/3420.htm.
22. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "Novel Drug Approvals for 2018." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm2020xx.htm. Notes: Number reflects NME approvals achieved by current Janssen Pharmaceutical companies.
23. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "CDER Breakthrough Therapy Designation Approvals." https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM481542.pdf.
24. U.S. Food and Drug Administration Briefing Document "Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee." February 12, 2019. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM630970.pdf.
25. The YODA Project. "Summary of Data Inquiries and Requests." http://yodavale.edu/table-3-data-requests-approved.
26. Janssen Pharmaceutical Companies of Johnson & Johnson. "Janssen Announces U.S. FDA Approval of SPRAVATO™ (esketamine) CIII Nasal Spray for Adults with Treatment-Resistant Depression (TRD) Who Have Cycled Through Multiple Treatments Without Relief." News release, March 5, 2019. https://www.janssen.com/janssen-announces-us-fda-approval-spravato-esketamine-ciii-nasal-spray-adults-treatment-resistant-
27. PhRMA. "The Dynamic U.S. Research and Development Ecosystem." 2018. https://www.phrma.org/industryprofile/2018/.
28. Prasad, Vinay, and Sham Mailankody. Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. JAMA Intern Med. 177, no. 11 (2017): 1569-1575.
29. DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansenc. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs". Journal of Health Economics 47, no. 5(2016):20-33.
30. Benson Carmela, Bruno Edmond, Hela Romdhani, Patrick Lefebvre, Azadeh Shohoudi, Neeta Tandon, and Keith Dunn. "Rapid Initiation of Antiretroviral Treatment Following Diagnosis of Human Immunodeficiency Virus Among Medicaid-covered Patients: A Real-world Evaluation. Poster #P384." HIV Drug Therapy: Glasgow 2018, October 28-31, 2018. Glasgow, United Kingdom.
31. Eikelboom, John W., Stuart J. Connolly, Jackie Bosch, Gilles R. Dagenais, Robert G. Hart, Olga Shestakovska, Rafael Diaz et al. "Rivaroxaban with or without aspirin in stable cardiovascular disease." New England Journal of Medicine377, no. 14 (2017): 1319-1330.
32. Bhatta, Madhav P., Saroj Bista, Antoine C. El Khoury, Eric G. Hutzell, Neeta Tandon, and Douglas Smith. "Encounters with the Criminal Justice System in Patients with Schizophrenia or Schizoaffective Disorders Treated with Long-Acting Therapy at a Community Mental Health Service Facility. Poster #220." 2018 Psych Congress, October 25-28, 2018. Orlando, Florida.
33. Muser, Erik, Chris M. Kozma, Carmela J. Benson, Lian Mao, H. Lynn Starr, Larry Alphs, and John Fastenau. "Cost Effectiveness of Paliperidone Palmitate Versus Oral Antipsychotics in Patients with Schizophrenia and a History of Criminal Justice Involvement."

REFERENCES

Journal of Medical Economics 18, no. 8 (May 6, 2015): 637-645.

34. American Cancer Society. "Cancer Facts & Figures 2018." 2018. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf.

35. World Health Organization (WHO). "Hepatitis B." July 2018. http://www.who.int/mediacentre/factsheets/fs204/en/.

36. Yuen, Man-Fung, Keven Liu, Bruce D. Given, Thomas Schluep, James Hamilton, Ching-Lung Lai, Stephen A. Locarnini, Kathy Jackson, Johnson YN Lau, Carlo Ferrari, and Robert G. Gish. "RNA Interference Therapy with ARC-520 Injection Results in Long Term Off-therapy Antigen Reductions in Treatment Naïve, HBeAg Positive and Negative Patients with Chronic HBV. Poster #FRI-362." EASL 2018, April 11-15, 2018. Paris, France. http://ir.arrowheadpharma.com/static-files/5b205068-35a4-41c9-942e-cb5ed100c2b2.

37. JLABS. Impact Report 2018. 2018. https://jlabs.jnjinnovation.com/about-us/impact-report.

38. Ross, Joseph S., Joanne Waldstreicher, Stephen Bamford, Jesse A. Berlin, Karla Childers, Nihar R. Desai, Ginger Gamble, Cary P. Gross, Richard Luntz, Richard Lehman, Peter Lins, Sandra A. Morris, Jessica D. Ritchie, and Harlan M. Krumholz. "Overview and experience of the YODA Project with clinical trial data sharing after 5 years." Scientific Data 5 (2018):180268 doi: 10.1038/sdata.2018.268.

39. The YODA Project. "Summary of Data Inquiries and Requests." http://yoda.yale.edu/table-3-data-requests-approved.

40. Ibid.

41. Ibid.

42. Bioethics International. "Bioethics International Releases the "Good Pharma Scorecard" in BMJ Open, Ranking the Top 20 Largest Pharmaceutical Companies on Clinical Trial Transparency." News release, December 5, 2017. https://www.prnewswire.com/news-releases/bioethics-international-releases-the-good-pharma-scorecard-in-bmj-open-ranking-the-top-20-largest-pharmaceutical-companies-on-clinical-trial-transparency-300566497.html.

43. Ibid.

44. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).

45. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "NDA and BLA Approval Reports – New Molecular Entity (NME) Drug and New Biologic Approvals." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm373420.htm.

46. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "Novel Drug Approvals for 2018." https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm. Notes: Number reflects NME approvals achieved by current Janssen Pharmaceutical companies.

47. U.S. Food and Drug Administration. "Priority Review." https://www.fda.gov/forpatients/approvals/fast/ucm405405.htm.

48. U.S. Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/.

49. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "CDER Breakthrough Therapy Designation Approvals." https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM481542.pdf.

50. U.S. Food and Drug Administration Briefing Document "Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee." February 12, 2019. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM630970.pdf.

51. U.S. Food and Drug Administration Center for Drug Evaluation and Research. "Breakthrough Therapy." U.S. Food and Drug

REFERENCES

Administration. January 4, 2018. https://www.fda.gov/ForPatients/Approvals/Fast/ucm405397.htm.

52. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
53. Figure according to Janssen internal financial accounting.
54. Ibid.
55. Ibid.
56. Johnson & Johnson has voluntarily posted the 2017 aggregated data for our companies covered by Open Payments, as submitted to CMS on March 31, 2018. Due to the CMS data review process, there may be differences between the aggregated totals for data posted here and aggregated totals derived from currently available data on the CMS website.
57. National Institute of General Medical Sciences. "Why Do Basic Research?" April 22, 2011. https://publications.nigms.nih.gov/basicresearch/#basic.
58. Li, Danielle, Pierre Azoulay, and Bhaven N. Sampat. "The Applied Value of Public Investments in Biomedical Research." Science 356, no. 6333 (2017): 78-81. doi:10.1126/science.aal0010.
59. Ibid.
60. Research!America. U.S. Investments in Medical and Health Research and Development, 2013-2017. Report. 2018. https://www.researchamerica.org/sites/default/files/Policy_Advocacy/2013-2017InvestmentReportFall2018.pdf
61. PhRMA. PhRMA Chart Packs: Biopharmaceuticals in Perspective. Report. 2018. http://phrma-docs.phrma.org/industryprofile/2018/pdfs/2018_IndustryProfile_Brochure.pdf.
62. Li, Danielle, Pierre Azoulay, and Bhaven N. Sampat. "The Applied Value of Public Investments in Biomedical Research." Science 356, no. 6333 (2017): 78-81. doi:10.1126/science.aal0010.
63. Johnson & Johnson, FY18-Q4 Form 10-K for the period ending December 30, 2018 (filed February 20, 2019).
64. Figure according to Janssen internal financial accounting.

Pricing & Patient Costs

65. IQVIA Institute for Human Data Science. Patient Affordability Part One: The Implications of Changing Benefit Design and High Cost-Sharing. Report. May 18, 2018. https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/patient-affordability-part-one---the-implications-of-changing-benefit-designs-and-high-cost-sharing.pdf?_=1552155560471.
66. Aetna. "Aetna to Provide Pharmacy Rebates at Time of Sale, Encourages Transparency from Drug Manufacturers." News release, March 27, 2018. https://news.aetna.com/news-releases/aetna-to-provide-pharmacy-rebates-at-time-of-sale-encourages-transparency-from-drug-manufacturers/
67. UnitedHealthcare. April 16, 2018. UnitedHealthcare implements point-of-sale discounts for eligible plan participants. https://www.uhc.com/employer/news/brokers/unitedhealthcare-implements-point-of-sale-discounts-for-eligible.
68. Kaiser Family Foundation. "Health Insurance Coverage of the Total Population." 2017. https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
69. PhRMA. PhRMA Chart Packs: Biopharmaceuticals in Perspective. Report. 2018. https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.
70. Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC).
71. Figure according to Janssen internal financial accounting.
72. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.
73. IQVIA Institute for Human Data Science. The Global Use of Medicine in 2019 and Outlook to 2023. Report. January 2019. https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023, pg. 11. Notes: 2018 Invoice price growth to YTD September 2018; Estimated net price growth in 2018 and forecast periods based on expected base case scenarios

REFERENCES

and interim review of selected company financial results; Protected Brands excludes new brands marketed less than 24 months in each year as price growth cannot be calculated.

74. U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2018." News release, January 11, 2019. https://www.bls.gov/news.release/archives/cpi_01112019.pdf.

75. U.S. Centers for Medicaid & Medicare Services. "National Health Expenditures 2017 Highlights." December 6, 2018. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

76. Ibid.

77. Pricing overview reflects U.S. Product Portfolio including pharmaceutical products marketed by the company. Products are primarily in the areas of Immunology, Oncology, Cardiovascular & Metabolism, Infectious Diseases, Neuroscience, and Pulmonary Arterial Hypertension.

78. Annual percent change vs. prior year calculated at product level and weighted across company's U.S. Product Portfolio.

79. Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC).

80. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.

81. IQVIA Institute for Human Data Science. The Global Use of Medicine in 2019 and Outlook to 2023. Report. January 2019. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf. Notes: 2018 Invoice price growth to YTD September 2018; Estimated net price growth in 2018 and forecast periods based on expected base case scenarios and interim review of selected company financial results; Protected Brands excludes new brands marketed less than 24 months in each year as price growth cannot be calculated.

82. U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2015." News release, January 20, 2016. https://www.bls.gov/news.release/archives/cpi_01202016.pdf.

83. U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2016." News release, January 18, 2017. https://www.bls.gov/news.release/archives/cpi_01182017.pdf.

84. U.S. Department of Labor. Bureau of Labor Statistics. "CONSUMER PRICE INDEX – DECEMBER 2018." News release, January 11, 2019. https://www.bls.gov/news.release/archives/cpi_01112019.pdf.

85. IQVIA INSTITUTE for Human Data Science. Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. Report. May 2017. https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.

86. The Henry J. Kaiser Family Foundation. "Distribution of Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2018." Figure. https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-5-market-shares-of-health-plans/attachment/figure-5-1/.

87. Peterson-Kaiser Health System Tracker. "Deductibles and Coinsurance Represent a Larger Share of Out-of-pocket Drug Spending Than 12 Years Ago." Figure. https://www.healthsystemtracker.org/chart-collection/recent-trends-characteristics-workers-high-drug-spending-2016/#item-deductibles-and-coinsurance-represent-a-larger-share-of-out-of-pocket-drug-spending-than-a-decade-ago.

88. Represents the year-over-year change in the average list price, or wholesale acquisition cost (WAC).

89. Represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns.

90. Figure according to Janssen internal financial accounting.

91. IQVIA INSTITUTE for Human Data Science. Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. Report. May 2017. https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.

92. PhRMA. Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines. Report. March 29, 2017. https://www.phrma.org/report/commercially-insured-

REFERENCES

patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines.

93. Claxton, Gary, Larry Levitt, Matthew Rae, and Bradley Sawyer. "Increases in Cost-sharing Payments Continue to Outpace Wage Growth." Peterson-Kaiser Health System Tracker. June 15, 2018. https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start.

94. Peterson-Kaiser Health System Tracker. "Deductibles and Coinsurance Represent a Larger Share of Out-of-pocket Drug Spending Than 12 Years Ago." Figure. https://www.healthsystemtracker.org/chart-collection/recent-trends-characteristics-workers-high-drug-spending-2016/#item-deductibles-and-coinsurance-represent-a-larger-share-of-out-of-pocket-drug-spending-than-a-decade-ago.

95. Ibid.

96. Udall, Margarita, Anthony Louder, Brandon T. Suehs, Joseph C. Cappelleri, Ashish V. Joshi, and Nick C. Patel. "Impact of a Step-Therapy Protocol for Pregabalin on Healthcare Utilization and Expenditures in a Commercial Population." Journal of Medical Economics 16, no. 6 (April 8, 2013): 784-92. doi:10.3111/13696998.2013.793692.

97. IQVIA Institute for Human Data Science. Patient Affordability Part Two: Implications for Patient Behavior and Therapy Consumption. Report. May 18, 2018. https://www.iqvia.com/locations/united-states/patient-affordability-part-two.

98. Heidari, P, Wendy Cross, Kimberley Crawford. "Do out-of-pocket costs affect medication adherence in adults with rheumatoid arthritis? A systematic review." Seminars in Arthritis and Rheumatism 48 no. 1 (August 2018): 12-21.

99. Farias A, Ryan N. Hansen, Steven B. Zeiladt, India J. Ornelas, Christopher I. Li, and Beti Thompson. "The Association Between Out-of-Pocket Costs and Adherence to Adjuvant Endocrine Therapy Among Newly Diagnosed Breast Cancer Patients." American Journal of Clinical Oncology 41, no. 7 (July 2018): 708-715.

100. Karter A, Melissa M. Parker, Matthew D. Solomon, Courtney R. Lyles, Alyce S. Adams, Howard H. Moffet, and Mary E. Reed. "Effect of Out-of-Pocket Cost on Medication Initiation, Adherence, and Persistence among Patients with Type 2 Diabetes: The Diabetes Study of Northern California." Health Services Research 53, no. 2 (April 2018): 1227-1247. https://onlinelibrary.wiley.com/doi/full/10.1111/1475-6773.12700.

101. Mcguire, Maura J., and Aurel O. Iuga. "Adherence and health care costs." Risk Management and Healthcare Policy 7, (2014): 35-44. doi:10.2147/rmhp.s19801.

102. IMS Institute for Healthcare informatics. Avoidable Costs in U.S. Healthcare The $200 Billion Opportunity from Using Medicines More Responsibly. Report. June 2013. https://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20_US_Healthcare-IHII_AvoidableCosts_2013%5B1%5D.pdf.

103. Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. Report. November 2012. https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf.

104. ConnectiveRx. (2018). Seeing Accumulator Adjustment Programs Through Patient's Eyes: 75% Say Their Adherence Would Suffer. https://www.mmm-online.com/wp-content/uploads/sites/2/2018/09/AccumulatorAdjustmentProgramsthroughPatientsEyes.pdf.

105. American Medical Association. 2018 AMA Prior Authorization (PA) Physician Survey. 2019. https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.

106. Aimed Alliance- Alliance for the Adoption of Innovations in Medicine. Putting Profits Before Patients: Provider Perspectives on Health Insurance Barriers that Harm Patients. Report. October 2018. https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey_Report.pdf

107. Global Healthy Living Foundation CreakyJoints. "New York Patient Sentiment Toward Non-Medical Drug Switching." https://creakyjoints.org/advocacy/new-york-patient-sentiment-toward-non-medical-drug-switching/.

A Message from Our Leaders
Our Investments
Pricing & Patient Costs
Advancing a Better Way
Resources for Patients
REFERENCES

REFERENCES

108. Alliance for Patient Access. National Online Survey: Key Findings from an Online Survey of 800 Non-Medical Switching Patients January 8-13, 2019.

109. Grabowski, Henry, Margaret Kyle, Richard Mortimer, Genia Long, and Noam Kirson. Evolving Brand-Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act. Report. November 2011. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2010.0270.

110. IMS Institute for Healthcare Informatics. Price Declines after Branded Medicines Lose Exclusivity in the U.S. Report. January 2016. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf?la=en&hash=0AA1C81204DBB674F83DA87EF2E2BB5ED02F3030.

111. The Henry J. Kaiser Family Foundation. "The Medicare Part D Prescription Drug Benefit." September 26, 2016. http://files.kff.org/attachment/Fact-Sheet-An-Overview-of-the-Medicare-Part-D-Prescription-Drug-Benefit.

112. PhRMA. Cancer Medicines: Value in Context. Report. 2018. http://phrma-docs.phrma.org/files/dmfile/PhRMA-Cancer-Chart-Pack-20181.PDF.

113. Bujar, Magdalena, Neil McAuslane, and Lawrence Liberti. R&D Briefing 62: New Drug Approvals in ICH Countries 2007 - 2016. Report. April 6, 2017. http://www.cirsci.org/wp-content/uploads/2017/04/ICH-Approval-Times-CIRS-Briefing-62-FINAL-18042017.pdf.

114. Zhang, Yuting, Hana Chantel Hueser, and Inmaculada Hernandez. "Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries." Journal of Managed Care & Specialty Pharmacy 23, no. 5 (2017): 601-04. doi:10.18553/jmcp.2017.23.5.601.

Advancing a Better Way

115. Gotto, Antonio M., Stephen J. Boccuzzi, John R. Cook, Charles M. Alexander, James B. Roehm, Gregg S. Meyer, Michael Clearfield, Stephen Weis, and Edwin Whitney. "Effect of Lovastatin on Cardiovascular Resource Utilization and Costs in The Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS)." The American Journal of Cardiology 86, no. 11 (2000): 1176-181. doi:10.1016/s0002-9149(00)01198-x.

116. IMS Institute for Healthcare Informatics. Avoidable Costs In U.S. Healthcare The $200 Billion Opportunity from Using Medicines More Responsibly. Report. June 2013. http://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20_US_Healthcare_IHII_Avoidable_Costs_2013%5B1%5D.pdf.

117. Altarum Institute, Center for Sustainable Health Spending Data Brief. "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail." 2014 & Addendum update August 2015. http://altarum.org/sites/default/files/uploaded-publication-files/Non-Retail%20Rx%20Forecast%20Data%20Brief_with%20Addendum.pdf.

118. Siegel, Rebecca L., Kimberly D. Miller, and Adhedin Jemal. "Cancer Statistics, 2019." CA Cancer J Clin 69, no.1 (2019): 7-34. doi: 10.3322/caac.21551.

119. Farnham, Paul G., Chaitra Gopalappa, Stephanie L. Sansom, Angela B. Hutchinson, John T. Brooks, Paul J. Weidle, Vincent C. Marconi, and David Rimland. "Updates of Lifetime Costs of Care and Quality-of-Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry Into Care." Journal of Acquired Immune Deficiency Syndromes 64, no. 2 (2013): 183-189. doi: 10.1097/QAI.0b013e3182973966

120. IQVIA Institute for Human Data Science. Medicine Use and Spending in the U.S. a Review of 2017 and Outlook to 2022. April 2018. https://www.iqvia.com/en/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

121. Lichtenberg, Frank. Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009. Working paper. The National Bureau of Economic Research. July 2012. doi:10.3386/w18235.

122. Perfetto, Eleanor M., Elisabeth M. Oehrlein, Marc Boutin, Sarah Reid, and Eric Gascho. "Value to Whom? The Patient Voice in the

REFERENCES

Value Discussion." Value in Health 20, no. 2 (February 2017): 286-91. doi:10.1016/j.jval.2016.11.014.

123. Neumann, Peter J., Theodore G. Ganiats, Louise B. Russell, Gillian D. Sanders, and Joanna E. Siegel. Cost-Effectiveness in Health and Medicine. New York: Oxford University Press, 2016.

124. Alphs, Larry, Carmela Benson, Kimberly Cheshire-Kinney, Jean-Pierre Lindenmayer, Lian Mao, Stephen C. Rodriguez, and H. Lynn Starr. "Real-World Outcomes of Paliperidone Palmitate Compared to Daily Oral Antipsychotic Therapy in Schizophrenia: A Randomized, Open-Label, Review Board-Blinded 15-Month Study." The Journal of Clinical Psychiatry 76, no. 5 (May 2015): 554-561. doi: 10.4088/JCP.14m09584.

125. Kim, David D., Colby L. Wilkinson, Elle F. Pope, James D. Chambers, Joshua T. Cohen, and Peter J. Neumann. "The Influence of Time Horizon on Results of Cost-Effectiveness Analyses." Expert Review of Pharmacoeconomics & Outcomes Research 17, no. 6 (May 23, 2017): 615-23. doi: 10.1080/14737167.2017.1331432.

126. Frieden, Thomas R. "Evidence for Health Decision Making – Beyond Randomized, Controlled Trials." New England Journal of Medicine 377, no. 5 (August 03, 2017): 465-75. doi:10.1056/nejmra1614394.

127. Neumann, Peter J., Theodore G. Ganiats, Louise B. Russell, Gillian D. Sanders, and Joanna E. Siegel. Cost-Effectiveness in Health and Medicine. New York: Oxford University Press, 2016.

128. Alphs, Larry, Carmela Benson, Kimberly Cheshire-Kinney, Jean-Pierre Lindenmayer, Lian Mao, Stephen C. Rodriguez, and H. Lynn Starr. "Real-World Outcomes of Paliperidone Palmitate Compared to Daily Oral Antipsychotic Therapy in Schizophrenia: A Randomized, Open-Label, Review Board-Blinded 15-Month Study." The Journal of Clinical Psychiatry 76, no. 5 (May 2015): 554-561. doi: 10.4088/JCP.14m09584.

129. Kim, David D., Colby L. Wilkinson, Elle F. Pope, James D. Chambers, Joshua T. Cohen, and Peter J. Neumann. "The Influence of Time Horizon on Results of Cost-Effectiveness Analyses." Expert Review of Pharmacoeconomics & Outcomes Research 17, no. 6 (May 23, 2017): 615-23. doi: 10.1080/14737167.2017.1331432.

130. Frieden, Thomas R. "Evidence for Health Decision Making – Beyond Randomized, Controlled Trials." New England Journal of Medicine 377, no. 5 (August 03, 2017): 465-75. doi:10.1056/nejmra1614394.

131. Westrich, Kimberly, MA. Current Landscape: Value Assessment Frameworks. Report. June 2016. http://www.npcnow.org/publication/current-landscape-value-assessment-frameworks.

132. Ibid.

133. Ibid.

134. Ibid.

135. Willke, R, Peter J. Neumann, Louis P. Garrison, Jr., and Scott D. Ramsey. "Review of Recent US Value Frameworks – A Health Economics Approach: An ISPOR Special Task Force Report." Value in Health 21, no. 2 (February 2018): 155-160. doi: https://doi.org/10.1016/j.jval.2017.12.011.

136. Garrison, LP, Peter J. Neumann, Richard J. Willke, Anirban Basu, Patricia M. Danzon, Jalpha A. Doshi, Michael F. Drummond, Darius N. Lakdawalla, Mark V. Pauly, Charles E. Phelps, Scott D. Ramsey, Adrian Towse, and Milton C. Weinstein. "A Health Economics Approach to US Value Assessment Frameworks – Summary and Recommendations of the ISPOR Special Task Force Report." Value in Health 21, no. 2 (February 2018): 161-165. doi: https://doi.org/10.1016/j.jval.2017.12.009.

137. Young-Xu, Yinong, Mei Sheng Duh, Erik Muser, Maral DerSarkissian, Elizabeth Faust, Andrew Kageleiry, Rachel H. Bhak, Dong-Jing Fu, Patrick Lefebvre, and Brian Shiner. "Impact of Paliperidone Palmitate Versus Oral Atypical Antipsychotics on Health Care Resource Use and Costs in Veterans with Schizophrenia." The Journal of clinical psychiatry 77, no. 10 (2016): e1332-e1341.

138. PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. Report. 2018. http://phrma-docs.phrma.org/files/dmfile/PhRMA-Value-of-Value-Based-Contracts1.pdf.

139. Richard Hirth, Elizabeth Cliff, Theresa Gibson, M. Richard McKellar, and A. Mark Fendrick. "Connecticut's Value-based Insurance Plan Increased the Use of Targeted Services and Medication Adherence." Health Affairs, 35 (4) (2016), pp. 637-646.

REFERENCES

140. Berwick, Donald M., Thomas W. Nolan, and John Whittington. "The Triple Aim: Care, Health, And Cost." Health Aff. 27, no. 3 (2008): 759-69. Doi.org/10.1377/hlthaff.27.3.759.

141. Harris, L. Jeff, Ilana Yonas, Pradeep S.B. Podila, Jim Wan, Teresa Waters, James Bailey. "Characteristics of Hospital and Emergency Care Super-utilizers with Multiple Chronic Conditions." J Emerg Med. 2016;50(4): e203-214. doi:10.1016/j.jemermed.2015.09.002.

142. Johnson, Tracy L., Deborah J. Rinehart, Josh Durfee, Daniel Brewer, Holly Batal, Joshua Blum, Carlos I. Oronce, Paul Melinkovich, and Patricia Gabow. "For Many Patients Who Use Large Amounts of Health Care Services, The Need Is Intense Yet Temporary." Health Aff. 2015;34(8):1312-1319. doi:10.1377/hlthaff.2014.1186.

143. Mann, Cindy. "Targeting Medicaid Super-Utilizers to Decrease Costs and Improve Quality." Baltimore, MD: Centers for Medicare and Medicaid Services. CMCS Informational Bulletin; 2013.

144. Chugh, Sumeet S., Rasmus Havmoeller, Kumar Narayanan, David Singh, Michiel Rienstra, Emelia J. Benjamin, Richard F. Gillum et al. "Worldwide Epidemiology of Atrial Fibrillation: A Global Burden of Disease 2010 Study." Circulation 129, no. 8 (2014): 837-847.

145. Centers for Disease Control and Prevention. "Atrial Fibrillation Fact Sheet." August 22, 2017. https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.

146. NCQA. "Population Health Management Resource Guide." May 21, 2018. https://www.ncqa.org/white_papers/population-health-management_resource-guide/.

147. Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. https://www.cbo.gov/publication/43741.

148. Mcguire, Maura J., and Aurel O. Iuga. "Adherence and health care costs." Risk Management and Healthcare Policy, 2014, 35-44. doi:10.2147/rmhp.s19801.

Resources for Patients

149. Van Nuys, Karen, Geoffrey Joyce, Rocio Ribero, and Dana P. Goldman. A Perspective on Prescription Drug Copayment Coupons. White paper. Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. February 2018. http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf.

150. O'Reilly, Kevin B. "Survey Quantifies Time Burdens of Prior Authorization." AMA Wire. January 30, 2017. https://wire.ama-assn.org/practice-management/survey-quantifies-time-burdens-prior-authorization

151. Data is an approximate number of patients supported by Janssen CarePath provided by the program administrator. In previous years this data included patients helped through Janssen CarePath separately from JANSSEN CONNECT®. In 2018, we expanded the Janssen CarePath program offerings to include resources previously provided under JANSSEN CONNECT®.

152. Ibid.

153. Based on product list price, or wholesale acquisition cost (WAC).

154. Data is an approximate number as reported by the Johnson & Johnson Patient Assistance Foundation, Inc.

155. According to internal financial accounting.

156. This estimate is based on assessment of donation amounts and publicly available data on approximate levels of patient assistance.

157. Partnership for Prescription Assistance. "About PPA." https://www.pparx.org/about_us.

158. According to Janssen's Pre-Approval Access global tracking system.


Janssen
Johnson & Johnson
JANSSEN GLOBAL SERVICES, LLC

EXHIBITS 14-80

CONFIDENTIAL – FILED UNDER SEAL

EXHIBIT 81

WITHDRAWN PENDING ORDER FROM JUDGE WOLFSON

EXHIBITS 82-147

CONFIDENTIAL – FILED UNDER SEAL

JJHCS Exhibit 1
CONFIDENTIAL – FILED UNDER SEAL

JJHCS EXHIBITS 2-8

CONFIDENTIAL – FILED UNDER SEAL

JJHCS Ex. 9

Patterson Belknap

www.pbwt.com

July 28, 2023

Julia Haigney Long
(212) 336-2878

VIA EMAIL

Elizabeth H. Snow, Esq.
Selendy Gay Elsberg, PLLC
1290 Avenue of the Americas
New York, NY 10104

Re: *Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC*
No. 2:22-cv-02632 (ES) (CLW)

Dear Elizabeth:

We write in response to your July 18, 2023 letter concerning organizational charts, custodians, and search terms.

I. Organizational Charts

A. Time Period

SaveOnSP asks for "organizational charts covering the full time period from April 1, 2016 through December 1, 2016." July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 1. To the extent any such relevant organizational charts exist, JJHCS agrees to produce them.

B. Juliette Deshaies

In your July 18 letter, SaveOnSP acknowledges that JJHCS has twice confirmed that Juliette Deshaies is an employee of JJHCS. Nevertheless, SaveOnSP continues to ask for "all organizational charts on which [Juliette Deshaies] appears, whether from JJHCS or Janssen." *Id.* For the avoidance of any doubt, Ms. Deshaies is a JJHCS—not "Janssen"—employee. To the extent that Ms. Deshaies worked in a department at JJHCS that was responsible for CarePath co-pay assistance, those organization charts already have been produced. JJHCS will not produce organizational charts from JJHCS departments without responsibility for the CarePath co-pay assistance program.

C. Groups in JJHCS's Organizational Charts

In your July 18 letter, SaveOnSP asks JJHCS to "explain the function" of fourteen groups named in JJHCS's organizational charts and to "provide the names of all members of each group, whether employed [by] JJHCS, at Janssen, or elsewhere in the J&J organization." *Id.* at 1-2. JJHCS declines. We are happy to work with you on good faith questions about the document

production process, but correspondence is not a forum for free-standing discovery beyond that permitted by the Federal Rules. Moreover, rather than a good faith effort to facilitate discovery, your query appears to be part of an ongoing and transparent attempt to restart the discovery clock *after* JJHCS named 17 custodians, produced thousands of documents, and was prepared to certify substantial completion.

II. Custodians

SaveOnSP asks JJHCS to "explain the function of the SMOX team and provide the names of all its members, whether employed at JJHCS or Janssen or elsewhere in the other J&J entities." *Id.* SMOX stands for "Supplier Management and Operational Excellence," and its team, which consists of 22 JJHCS employees, is tasked with supply-related adherence and compliance at JJHCS. John Paul Franz leads the SMOX team. To the extent that SMOX members worked on any relevant issues, we have produced those documents. Further discovery regarding SMOX is irrelevant.

As to individuals, JJHCS is prepared to add Quinton Kinne and Daphe Longbothum as custodians, subject to (1) those additions resolving this dispute about custodians and (2) SaveOnSP agreeing to add Ms. Ayesha Zulqarnain as an additional SaveOnSP custodian per our recent request. Absent such agreement, for the reasons discussed below, JJHCS declines to add the requested custodians.

A. Quinton Kinne

SaveOnSP first proposed Mr. Kinne as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 letter. SaveOnSP now again seeks his addition. The documents relied upon by SaveOnSP are unpersuasive to justify adding Mr. Kinne as an additional custodian. The email chain that SaveOnSP seeks in JJHCS_00035757 will be captured by other custodians from whom JJHCS has agreed to produce documents, including Lindsey Anderson, who is specifically mentioned in the document cited by SaveOnSP. July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 3. Nonetheless, given your repeated requests and in the interests of compromise, we are willing to add Mr. Kinne on the terms detailed above.

B. Leigh Wyszkowski

JJHCS declines to add Leigh Wyszkowski as an additional custodian. SaveOnSP first proposed Ms. Wyszkowski as a custodian on March 7, 2023. JJHCS declined this request in its March 16, 2023 letter and informed SaveOnSP that Ms. Wyszkowski's documents and communications "will be captured by other custodians from whom JJHCS has agreed to produce documents, including John Paul Franz, to whom Ms. Wyszkowski reported." March 16, 2023 Ltr. from H. Sandick to A. Dunlap at 4. SaveOnSP now makes the exact same request when nothing has changed in the last four months. In addition, SaveOnSP's reliance on JJHCS_00008989 is misplaced. Even if Mr. Kinne had "one-on-one meetings" with Ms. Wyszkowski, it does not follow that those meetings would have generated relevant email traffic. As JJHCS has repeatedly stated, Mr. Kinne and Ms. Wyszkowski are in the same reporting line and all responsive documents

would be captured by John Paul Franz's documents. Moreover, as noted above, we have now offered to add Mr. Kinne.

C. Daphne Longbothum

SaveOnSP first proposed Ms. Longbothum as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 letter and informed SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Ms. Longbothum would have unique documents or communications relating to SaveOnSP" and that her documents would be cumulative of "other custodians from whom JJHCS has agreed to produce documents, including Nidhi Saxena and Hattie McKelvey, to whom Ms. Longbothum reported." May 19, 2023 Ltr. from H. Sandick to E. Snow at 2. SaveOnSP asks again, relying on the fact that "Ms. Longbothum's documents are not coextensive with Saxena's and McKelvey's documents" because they do not appear on three emails that Ms. Longbothum received. July 18, 2023 Ltr. from E. Snow to G. LoBiondo at 3-4. SaveOnSP's reliance on JJHCS_00001393 and JJHCS_00034500 is peculiar. Ms. Longbothum is neither the sender, nor the sole receiver of these emails and, more importantly, is not involved in the discussion. Similarly, in JJHCS_00034526 is an email from Ms. Longbothum to Adrienne Minecci, an agreed-upon custodian. Any relevant part of that conversation would be captured by Ms. Minecci's documents or communications. Nonetheless, given your repeated requests and in the interests of compromise, we are willing to add Ms. Longbothum on the terms detailed above.

D. William Shontz

JJHCS declines to add William Shontz as an additional custodian. SaveOnSP first proposed Mr. Shontz as a custodian on May 9, 2023. JJHCS declined this request in its May 19, 2023 letter and its June 23, 2023 joint letter informing SaveOnSP that "based on its investigation, JJHCS has no reason to believe that Mr. Shontz would have unique documents or communications relevant to the litigation, or that any such documents would not be cumulative of those produced from existing JJHCS custodians, Hattie McKelvey and Silviya McCool, to whom he reports." June 23, 2023 Joint Letter at 11. SaveOnSP asks again, claiming that Mr. Shontz's "documents are not completely captured by McKelvey or McCool." None of those documents merit adding Mr. Shonz. For example, SaveOnSP's reliance on JJHCS_00001202 to state that [redacted] is insufficient to add him as an additional custodian. [redacted] JJHCS_00001202 at 3. A four-day gap in coverage is hardly a reason to justify adding Mr. Shontz as a custodian. Furthermore, SaveOnSP's reliance on JJHCS_00008556, JJHCS_00034500, and JJHCS_00034531 is peculiar. Mr. Shontz is neither the sender, nor the sole receiver of these emails and, more importantly, is not involved in the discussion. This is wholly insufficient to add Mr. Shontz as an additional custodian.

E. Alison Barklage

JJHCS declines to add Alison Barklage as an additional custodian. Based on its investigation to date, Ms. Barklage served as a JJHCS contractor during the relevant period with administrative responsibilities. To the extent Ms. Barklage's custodial files contain relevant documents or communications, they would be cumulative of those produced by JJHCS from other

agreed-upon custodians, including Heith Jeffcoat, to whom Ms. Barklage reported, and Quinton Kinne, with whom Ms. Barklage worked.

III. Search Terms

JJHCS declines to add the search strings proposed by SaveOnSP in its July 18 letter. SaveOnSP has failed to propose any narrow supplemental search terms designed to search for particular documents. As such, we can only assume that these demands are intended to impose burden rather than a good faith effort to yield relevant discovery. As a threshold matter, two of SaveOnSP's proposed search strings containing the term "co-ins*" were too expansive to even be run in our database. JJHCS understands that when a modifier like "!" or "*" is used, the term can only be run if it generates less than 2,000 unique word hits. "Co-ins*" returned too many unique words to be run. In an effort to approximate SaveOnSP's requests, JJHCS has replaced that term with "co-insur*" in the chart below.

A typographical error in a third search string also prevented JJHCS from running the string: (CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay or payment or contrib*)) pay* w/100 (patient w/10 ("high deduc*) OR "high-deduc* OR "health savings" OR HSA). Again, in an effort to approximate SaveOnSP's requests, JJHCS has run this term as two strings "(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay or payment or contrib*))" and "pay* w/100 (patient w/10 ("high deduc*) OR "high-deduc* OR "health savings" OR HSA)."

JJHCS also declines to add these search strings based on the unduly burdensome number of additional unique documents hitting on these terms for the April 1, 2016 to July 1, 2022 time period. As summarized in the chart below, these nine terms would require JJHCS to review 296,475 unique documents including families—before adding either Quinton Kinne or Daphne Longbothum as custodians. At this stage in the litigation, this wholesale re-opening of discovery is simply unwarranted. We therefore decline to agree to these additional search terms.

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
CAP OR CAPm OR CAPa	86,548	181,765

[1] These hit counts exclude documents that have already been reviewed in the course of this litigation.

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") AND (patient w/20 (copay OR payment OR contrib*))	32,385	112,425
(Accredo OR Acredo) w/50 (accumulat* OR maximiz* OR copay* OR co-pay* OR coins* OR co-insur* OR "cost share")	4,087	8,883
Copay w/5 max*	3,685	20,573
copay assistance w/10 program	3,359	20,616
Copay w/5 accumulat*	3,337	10,592
("Express Scripts" OR ESI OR ExpressScripts) w/50 (accumulat* OR maximiz* OR copay* OR co-pay* OR coins* OR co-insur* OR "cost share")	2,140	10,594

Search Term Proposed by SaveOnSP	Additional Documents Hitting on Term[1]	Additional Documents Hitting on Term + Families
(CarePath OR "Care Path" OR CP OR JCP OR "Savings Program") w/100 (ACA OR "Affordable Care Act" OR Obamacare)	1,268	4,806
pay* w/100 (patient w/10 ("high deduc* OR" high-deduc* OR "health savings" OR HSA))	819	2,673

Very truly yours,

/s/ Julia Haigney Long
Julia Haigney Long